AN OPEN CLINICAL TRIAL OF SIDDHA HERBAL FORMULATION "THATHU VIRUTHI KULIGAI" (INTERNAL) IN THE TREATMENT OF AANMALADU" (MALE INFERTILITY)

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "AN OPEN CLINICAL TRIAL OF SIDDHA HERBAL FORMULATION **"THATHU VIRUTHI KULIGAI"** IN THE TREATMENT OF **AAN MALADU [MALE INFRTILITY]**" under the Guidance of **Dr.H. VETHA MERLIN KUMARI M.D(s)**, Ph.D, Lecturer, Department of Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation work has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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CONTENTS

CONTENTS

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INTRODUCTION

AIM AND OBJECTIVES

REVIEW OF LITERATURE
SIDDHA ASPECT

MODERN ASPECT

MATERIAL & METHODS

PROTOCOL

DRUG REVIEW

ANALYSIS

PHYSIOCHEMICAL ANALYSIS

PHYTOCHEMICAL ANALYSIS

BIOCHEMICAL ANALYSIS

OBSERVATION AND RESULTS

DISCUSSION

CONCLUSION

SUMMARY

REFERENCES

ANNEXURE

INTRODUCTION

Siddha system of medicine is a holistic medical system which has been developed gradually during the consecutive era. Siddha medicine is a comprehensive system of medicine and this is briefly described by Siddhars.Siddhar (Sage) is a tamil word that is derived from its word "Chit" which means **"PERFECTION ORHEAVENLY BLISS**".

Ancient Siddhars had the knowledge and wisdom to find treatments to the day problems through single herb, Polyherbal, Herbo mineral and sometimes animal by-products. According to the siddha science all the things in the universe both inside and outside the body are made up of five basic elaments namely **SPACE, AIR, FIRE, WATER AND SOIL** in balanced proportions.

In south India siddha still remains dominant compared to modern medicine particularly for the treatment of a variety of chronic disease conditions among masses. The basic motto of siddha science is "**FOOD ITSELF A MEDICINE AND MEDICINE ITSELF IS FOOD''.** Siddha medicine is not only used to treat diseases. Apart from this it also acts as a Prophylaxis to prevent the diseases. "**An Ounce of Prevention is Worth a pound of cure".** There are so many ways such as Kayakalpam, Yoga, Pranayama…ect to prevent the diseases. Pathyam (Balanced diet) plays a unique role in siddha medicine to prevent further complications of the existed diseases. The only hope is that we should make a scientific study of Siddhars ancient medical works to the Enlightment of medical field. A remarkable increase in the usage of medicinal plant products in the form of plant extracts and their active components etc. Have been observed in the past decade, among the world population as a primary health care aid.

One of our great Saint Yugi muni classified the diseases into 4448. AAN MALADU is disease one among them. According to Yugi muni in aanmaladu the semen exhibits the following characters such as absence of sweetness, buoyancy on water. He further explained the character of urine in aanmaldu as froth in urine and symptoms like absence of virility.

The most important part of siddha medicine is **7 UDAL THADHU** i. e (SARAM, SENEER, OON, KOZHUPU, ENBU, MOOLAI, SUKKILAM, SURONITHAM). Sukkilam is one among the seven udalthathukkal and it is affected in Aanmaladu. It can be termed as with male Infertility in modern science. Most cases of male infertility are due to an abnormal sperm count or low sperm motility. Infertility is the inability of a sexually active, non-contraception couple to achieve pregnancy in one year. In former days Infertility is only accompanied with women. But nowadays due to sedentary lifestyle it is also accompanied with men. Male infertility is blamed in 50 % of cases where couples could not conceive naturally. Male infertility is a global problem in the field of reproductive health.

Infertility bears a social stigma. In couples experiencing infertility, approximately 35% is due to male factors, 35% is due to female factors, 20% of cases have a combination of both male and female factors and the last 10% are unexplained causes.

Most of the cases hail from IT back ground, chemical industry, oil refineraries, viral infections at an early age in male child, trauma in testes, endocrine disorder, low economic status, can also lead to rise in infertility rate. The heat generated from laptops can make an impact sperm production and development making it difficult to conceive down the road. As per WHO guidelines a report with count less than 20 million / ml is oligospermia. Oligospermia is a male fertility issue defined as a low sperm concentration in the ejaculation. The most common problems a man facesare low sperm count, morphology abnormalities and motility of sperm.

This current research study entitled Aanmaladu (Male infertility) mainly focus on outcome of qualitative and quantitative analysis of semen in oligospermia patients with the trial drug **THADHU VIRUTHI KULIGAI**. Thadhuviruthikuligai is a polyherbal compound based on the ingredients of the drug. The trial drug Thadhuviruthikuligai being the poly herbal formulation consists of ingredients possessing anti oxidants (kayakalpha drugs) and aphrodisiac properties.

Since the trial medicines is yet to be documented for its efficacy, it is essential to do safety going for clinical study.

AIM AND OBJECTIVES

Aim:

To document the effective of Siddha Medicine Thadhu viruthi kuligai (Internal medicines) in the management of AAN MALADU (male infertility)

***Primary Objective*:**

To evaluate the therapeutic efficacy of Thadhu viruthi kuligai (Internalmedicines) based on Semen analysis in the treatment of ***AAN MALADU*** (male infertility)

Secondary Objective:

- To prepare the trial Medicine as per the text**NOIGALAKU** *SIDDHA MARUTHUVAPARIGARAM.*
- To collect raw drugs and to get Authentication.
- To evaluate the phytochemical analysis of the drug.
- To study the changes in special investigation –Semen Analysis Before andAfter treatment.
- To evaluate the Infertility Percentage among the study patients with respect to age, occupation, and socioeconomic structure

ஆண்மலடு

“பார்க்கவேஆண்மகனின்விந்துதானும்
பதமானதிதிப்புயில்லாததாலும்
ஏற்கவேசலமீதில்மிதந்ததாலும்
எழிலாகவுயிர்ப்பற்றுயிருப்பதாலும்
சேர்க்கவேமூத்திரத்தில்நுரைதான்போலும்
செயலானகருவதுவும்தரிக்கமாட்டா
தீர்க்கவேயூகிமுனிசிகிச்சாரம்
தெளிவாகப்பாடிவைத்தார்திறமிதானே”

- *யூகிமுனி*

The characteristics of semen in AAN MALADU

The presence of semen in aanmaladu is lack of sweetness and life then it will float on the surface of water.

The urine also will be frothy. Such man will be incapable to give succeeding generation.

DEVELOPMENT OF SPERM

“உதயத்தில்விந்துவில்ஓங்குகுண்டலியும்
உதயகுடிலில்வயிந்தவம்ஓன்பான்
விதியில்பிரமாதிகள்மிகுசத்தி
கதியிற்கரணங்கலைவைகரியே!”

-திருமூலர்

In the above verses Thirumolar states that the driving force of the kundalini arises in the sperm which in turn initates the anthakarnanam to bring changes in the ova during fertilization.

5 ARTS OF SPERM

1. Neekal
2. Nelaipithal
3. Nugarvithal
4. Amaithiyakkal
5. Appalakkal

CONFIGURATION OF SEMEN

Based on siddha principles the semen is constituent by eighty drops of blood which is equal to one drop of semen. Therefore, even wasting a single drop of semen is equal to wasting six thousand four hundred drops of blood.

“அழிகின்றவிந்துஅளவைஅறியார்
கழிகின்றதன்னையுட்காக்கலுந்தேரார்
அழிகின்றகாயத்தழிந்தயர்வுற்றோர்
அழிகின்றதன்மையறிந்தொழியாரோ!”

--- திருமூலர் - பாடல் - 1936

In the above verses states about the significance of sperm. In modern comparison the process of spermatogenesis in which the male gamete called spermatozoa are formed by four stages like proliferation, growth, maturation, transformation.

SIGNIFICANCE OF SPERM

“விந்துநிலையறிந்துவுந்துபாயுங்காலம்தேவதாந்தநாதமதுக்குயிருண்டாகிசொந்த முடனேயிரண்டுமணியுமாகிச்சோதிமணியானதுவிம்பிறையுமாகிவந்தமதிப்பிறை யதுவும்வட்டமாகி வட்டமதிரண்டுருவாய்மண்ணுமாகி
அந்தமுள்ளமண்ணுதற்உப்பாய்நின்றே யாதியென்றபொருளானபிண்டமாச்சே”

-அகத்தியர்

After the penetration of the sperm into the ovum the sperm head fuse with the oocytic cell to form single cell. Then it undergoes several stages of cell division to form an embryo.

“விழுந்ததுஇலிங்கம்விரிந்ததுயோனி
ஒழிந்தமுதல்ஐந்தும்ஈரைந்தோடுஏறிப்
பொழிந்தபுனல்பூதம்போற்றும்கரணம்
ஒழிந்தநுதல்உச்சிஉள்ளேஒளித்ததே!”

- திருமூலர்.

At the time of copulation, the semen is ejaculated. The prostatic fluid gives the semen as a milky appearance. In the early stages after ejaculation, the sperm remains immotile, possibly because of the viscosity of the coagulum. As the coagulum dissolves the sperm become highly motile.

“ஆண்மிகில்ஆண்ஆகும்பெண்மிகில்பெண்ஆகும்
பூண்இரணடொத்துப்பொருந்தில்அலிஆகும்
தாண்மிகும்ஆகில்தரணிமுழுதாளும்
பாணவமிக்கிடில்பாய்ந்ததும்இல்லையே.

-திருமூலர்

At the time of copulation if the male dominates then it is male & if the female dominates then it is a female child. If the male and the female are equal then the child will be neutral gender or a eunuch. Here male indicates the vindhu and the female indicates nadham.

“வேர்க்கவேவேலிபோல்வளைந்துகாக்கும்
விந்துவுடன்பிராணவாயுவிளக்கலாமே”

-யூகிமுனி

Abana stays outside of uterus and the prana goes along with spermatozoa and bisects the size of the zygote.

“உன்னியகர்ப்பக்குழியாம்வெளியிலே
பன்னியநாதம்பகர்ந்தபிருத்வி
வன்னியும்வாயுவமாயுருஞ்சுக்கிலம்
மன்னியசமனாய்வளர்க்குமுதகமே”

-திருமூலர்

The ovum consists of the element earth, whereas the sperm consist of fire and air. The uterine wall which nourishes it bring water and the urine cavity is of the element space. Therefore, in the formation embryo of five elements combine and create it.

“விந்துகுடியிருந்ததிருநாட்டைவிட்டேன்
மாறுகின்றகத்தரிக்கோல்பட்டந்தனில்
விந்துநின்றுவிளங்குநதிமையத்துள்ளே
விளங்குசுவாதிட்டானவெளியிலேதான்”

-திருவள்ளுவர்ஞானவெட்டியான்

The swadhittanam is to be found between the genital and navel region. The swadhittanam is correlated with adrenal gland which secretes testosterone.

சுக்கிலம்குணம்

“உண்மையானசுக்கிலமுபாயமாயிருந்ததும்
வெண்மையாகிநீரிலேவிரைந்துநீரதானதும்
தண்மையானகாயமேதரித்துருவமானதும்
தெண்மையானஞானிகள்தெளிந்துரைக்கவேணுமே”

-சிவவாக்கியர்பாடல்எண்.1236----

In the above verses Sivavakiyaar states that the sperm moves through the vagina in a tricky way and mixes with the internal secretions and finally to form a “*DEW DROP*”. This dew drop enhances the growth of ovum.

Modern comparison:

Basic physiological concept of Sperm states that the movement of the sperm through the uterus is facilitated by the anti peristaltic contractions of uterine muscles among 200-300 million of sperm entering female genital tract in that only a few thousand sperm reach the spot near ovum. Among these few thousand sperm only one is capable for fertilization with ovum.

DIAGNOSIS OF DISEASE BY CHARACTERS OF SEMEN:

1. White and akin to the butter, it is excellent.
2. White and curd, it is very good.
3. White and akin to the milk, it is good.
4. White and akin to the buttermilk, it is fair.
5. Akin to the honey in colour and consistency, it is average.
6. Akin to the ghee in colour and weight, it is poor.
7. Akin to the toddy in colour and thickness it is poor.
8. Akin to the water, it is very bad.

SIDDHA PATHOLOGY

The subtle form of primordial elements

1. Earth
2. Water
3. Fire
4. Air
5. Space

In the above the Air element aggravates the urethral pain during purulent discharge from urethra.

The properties of object having the five elemental components

1. Earth - Bulk
2. Water –Soft, giving pleasure, coolness soaking, viscid, slimy and flowing of semen.
3. Fire -Hot
4. Air - Denselessness
5. Space – Sharp and clear

The properties of taste

The ill effect caused by excessive intake of saltiest food leads to a gradual loss of vitality and vigor.

The ill effect caused by excessive intake of pungent food leads to **impotency**

Based on Five Motor Organs

1. Mouth
2. Legs
3. Hands
4. Excretory Organs
5. Reproductive Organs - Reproductive Organs causes Ejaculation, and ensures pleasure on account of reproduction.

The Ten Channels (DasaNaadi)

1. Idakalai
2. Pingalai
3. Suzhumunai
4. Siguvai

5. Purudan
6. Kanthari
7. Aththi
8. Alampudai
9. Sangini
10. Gugu.

- ✓ Sangini – Located in Genital Organs.
- ✓ Gugu – Located in Anorectal region.

The five kinds of Aasayams:

1. Amarvasayam
2. Pakirvasayam
3. Salavasayam
4. Malavasayam
5. Sukkilavasayam – specified activities are semen secretion and storage.

KOSAM (FIVE SHEATHS):

1. Aanamayakosam
2. Pranamayakosam
3. Manomayakosam – constituted by the Mind and the Sense organs
4. Vingnanamayakosam

EIGHT PASSIONS:

1. Kaamam
2. Kurotham
3. Lopam
4. Mokam
5. Madham
6. Maacharyam
7. Idumbai
8. Ahankaram

***KAAMAM – Sexual desire**

THE THREE HUMOURS

1. Vatham
2. Pitham
3. Kapham

VATHAM- 10 different types:

1. Pranan
2. Abanan
3. Vyanan
4. Udhyanan
5. Samanan
6. Nagan
7. Koorman
8. Kirukaran
9. Devadhaththan
10. Dhananjayan.

Abanan – The downward Air. Responsible for excretion of urine, faeces and semen

Vyanan – Activates the Voluntary and involuntary muscles.

Devadaththan – Attributes human passions.

PITHAM 5 different types:

Anaandhamaya Kosam – constituted by the Prana and Reproductiom

1. Analpasakapitham
2. Vanna eri
3. Aatralankai
4. Ulloli thee
5. Nokkazhal

AATRALANKAI – improves Blood

ULLOLI THEE – gives color and brightness to the skin.

KAPHAM – 5 different types:

1. Ali aiyum
2. Neerpiaiyum
3. Suvaikaanaiyam
4. niraivuaiyam
5. Onriayam

Seats of kabham- Urinary bladder, Genital organs which makes the urine and Semen come out of the body.

SEVEN PHYSICAL CONSTITUTIONS

1. **Saarum** (Chyle): This gives mental and physical perseverance.
2. **Senneer** (Blood): Imparts colour to the body, nourishes the body and is responsible for the Ally and intellect of an individual
3. **Oon**(Muscle): It gives shape to the body according to the physical activity and covers bone.
4. **Kozhuppu** (Adipose tissue): it lubricates the joints and other parts of the body to function smoothly
5. **Enbu** (Bone): Supports the frame and responsible for the postures and movements of body.
6. **Moolai**(Bone marrow): It occupies the medulla of the bones and gives strength and softness to the muscles.
7. **Sukkilam** (Sperm): It is responsible for reproduction.

- Excess Sukilam causes love and lust towards women and urinary calculi.
- Decreased sukkilam causes failure in reproduction, pain in the genitalia etc.

FOURTEEN NATURAL URGES

Semen is the one of the fourteen urges

“சுக்கிலந்தனையடக்கின்
சுரமுடனீர்க்கட்டாகும்
பக்கமாங்கைகால்சந்து
பாரநோய்வழியிறங்கும்
மிக்கமார்நோயுண்டாகும்
மிகுத்திடும்பிரமேகந்தான்
தக்கதோர்போதுமாகின்
தரித்திடும்வாயுக்கூறே” **-சித்தமருத்துவாங்கசுருக்கம்**

If Semen is controlled, it leads to fever, oliguria, joint pain, urinary infection, spermatorrhoea, Leucorrhoea and chest pain.

Significance of sperm implantation period:

Implantation of sperm occurs few days before full moon leads to unhappiness.

- Implantation of sperm occur six days after full moon leads to happiness
- Four mugurthams before dawn is the right time to implantation of sperm
- One mugurtham is equal to one and a half hour

சுக்கிலவாதம்

வாதமாமுடலுருகிகவும்வற்றி
மலமூத்திரஞ்சிக்கியேகீழ்விழாமல்
நாதமாம்நாக்கோடுமூக்குதன்னில்
நாணுக்கமாயுதிரந்தனருவிபாயுஞ்
செயவோடுசுவாசமாயருசியுண்டாஞ்
சூதமாய்ச்சுக்கிலந்தான்றுன்னியாகுந்
துரியசுக்கிலவாதசூட்சந்தானே.

- யூகிமுனி

Symptoms associated with sukkilam

In the above verses yugi muni states that

1. Emaciation
2. Constipation
3. Oliguria
4. Bleeding from the nose
5. Phlegm accumulation due to increased kapham, breathlessness
6. Loss of taste

All the symptoms are associated with affected sukkilam**.**

DIFFERNTIAL DIAGNOSIS:

வாதஉபகதம்

ஆண்மையாங் காலோடு கையுஞ் சந்து
அங்க மெலா மிகத்திமிர்ந்து சாணி தானும்
பூண்மையாப் பூசினது போலே காணும்
புரண்டுதான் விறுவிறுத்துப் புளக மாகிப்
பாண்மையாங் காதசையு முஷ்ணமாகிப்
பசித்துமே மிகநாணி நடைகொடாது
வாண்மையாம் வாட்டமுறு மயக்க மாகும்
வாதவுப கதந்தன்னை வகுத்த வாறே!

-யூகி முனி வாத காவியம்

Numbness of joints of upper and lower limbs, increased body heat, appetite, excessive tiredness and inability to walk, giddiness.

பதிதவாதம்

காரியாய் மிகவார்த்தை பேசும் போது
கழுத்திலுள நரம்புமிக விசைத்து நோவாம்
வாரியாய் வார்த்தைகள்தான் விக்கிப் பேசி
வார்த்தைகள்தான் பேசு வதிற் றெரிந்தி டாது
நாரியார் போகமது விரும்பி டாது
நலுக்கமாய்த் தாதுவெலா மிளைத்துக் காணும்
பாரியா யடிக்கடிக்குப் பசியே யுண்டாகும்
பதிதமாம் வாதமென்றே பகர லாமே!

-யூகி முனி வாத காவியம்

Due to over talking more pain wil be felt neck aggravated in the cervical plexus. Loss of sexual, general weakness, increased appetite.

LINE OF TREATMENT

The main aim of the Siddha system is to treat and to cure Udarpini (due to Mukkuttram) and Manapini (due to changes in Mukkunam). Treatment is not only for perfect healing but also for the prevention and rejuvenation.

It is essential to know the disease, the aetiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence must be observed clearly. Line of treatment is as follows:

1. Neekkam (Treatment)
2. Niraivu (Rejuvenation)
3. Kaapu (Prevention)

Thiruvalluvar describes the duty of the physician, i.e. study the disease, aetiology, seek subsiding ways and do what is proper and effective.

"நோய் நாடி நோய் முதல் நாடி அது தணிக்கும்
வாய் நாடி வாய்ப்பச் செயல்"
"உற்றானளவும் பிணியளவுங் காலமும்
கற்றான் கருதிச் செயல்"

- திருக்குறள்.

1) NEEKKAM (Treatment in Siddha):

The aim of Neekkam is based on to bring the deranged Thodams to normal equilibrium state. To treat the patient with internal medicine and external medicine

Siddha system of Medicine is based on Mukkutra Theory and hence the treatment is mainly aimed to bring the three thodams to equilibrium state and thereby restoring the physiological condition of the seven Thathus.

The three Thodamsorganise, regularise and integrate the body structure and their functions. They are always kept in a state of balance by thought, word, deed and food. Any imbalance will lead to disease. The imbalanced thodams are balanced by administrating purgatives or emetics or application of Anjanam (application on eyes) and followed by the appropriate systemic therapy by giving Siddha drugs.

"விரேசனத்தால் வாதந் தாழும்"
"வமனத்தால் பித்தம் தாழும்"
"நசிய அஞ்சனத்தால் கபம் தாழும்"

- சித்த மருத்துவாங்கச்சுருக்கம்

Before treating with the trail drug, the patients were advised to take oil bath with ArrakuThylam to normalize the vitiated pitham to equilibrium.The purgatives should be given before starting the trial to normalize the deranged Thodams to normal.

In this study the purgation is induced by giving Agasthiyarkulambu - 130 mg with hot water in early morning in empty stomach.

2) NIRAIVU (Rejuvenation):

The word literally means the power of securing the body from the effect ofage. According to Siddhars science rejuvenation does not necessarily mean restoring the oldto youth for it may simply mean the maintenance of youth without reaching the old age.

So, rejuvenation is a means for prolonging life & forms a part of immortality.

T.V. Sambasivampillai, Dictionary.

(Physical, psychological, social and economic rehabilitation and reassurance of Individuals are known as Niraivu).

3. KAAPPU (PREVENTION):

The prevention methods for AanMaladu are as follows:

- Advised to take oil bath twice a week.
- Advised to avoid smoking alcohol and using tobacco of any kind.
- Advised to avoid sour rich food suffs.

4) DIETARY RESTRICTIONS:

In siddha system of medicine, the importance of dietary habits also emphasiszed for the diseases management and prevention. This line is well understood in these verses,

"உணவே மருந்து மருந்தே உணவு".

"மருந்தென வேண்டாவாம் யாக்கைக்கு அருந்தியது
அற்றது போற்றி உணின்". ***- திருக்குறள்***

In diseased condition diet restrictions or paththiyam are strictly followed to increase the effectiveness of medicine, and to reducing the severity of diseases. This is given in the following verse,

"பத்தியத்தினாலே பலன் உண்டாகும் மருந்து
பத்தியங்கள் போனால்பலன்போகும் - பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பார்"

- தேரையர் வெண்பா.

இச்சா பத்தியத்தில் நீக்கும் பொருட்கள்:

"கடுகு நற்றிலத் தெண்ணைய் கூழ்பாண்டங்கள் கடலை
வருவதாகிய தெங்குமா வருக்கை நற்காயம்
மடிவிலாத வெள்ளுள்ளிகொள் புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச்சா பத்தியம்"

- சித்த மருத்துவாங்கச்சுருக்கம்

கடுகு, எள்நெய், கல்யாணபூசணிக்காய், கள், கடலை, தேங்காய், மாங்காய், பலா, காயம், உள்ளிப்பூண்டு, கொள், புகையிலை, பெண்கள் சேர்க்கை, பாகல், அகத்தி இவைகளை இச்சா பத்தியத்தில் நீக்க வேண்டும்.

"புளிதுவர் விஞ்சும் கறியால்பூரிக்கும் வாதம்"

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு

"தாளிமுருங்கைத்தழைதூதுளம்பசலை
வாளிலறுகீரையுநெய்வார்த்துண்ணி- லாளியென
விஞ்சுவார்போகத்தில்வீம்புரைத்தபெண்களெலாங்
கெஞ்சுவார்பின்வாங்கிக்கேள்"

-குணபாடம்மூலிகைவகுப்பு

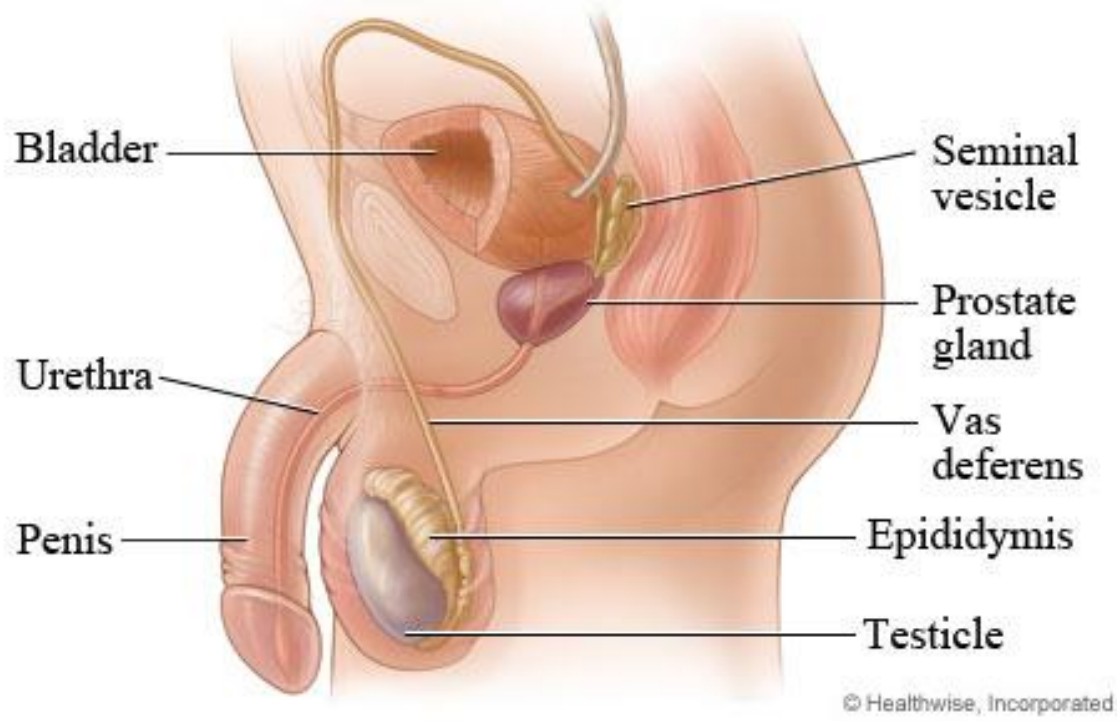
நறுந்தாளி, நன்முருங்கை, தூதுணம், பசலை, அறுகீரை இவற்றுள் யாதேனும் ஒன்றை புளி நீக்கிச் சமைத்து நெய்சேர்த்துக் காலையில் மாத்திரம் நாற்பது நாள் உண்ண, ஆண்மைப்பெருகும்.

தவிர்க்கவேண்டியவை:

- **பகற்பொழுதில்புணர்ச்சியில்ஈடுபடக்கூடாது**
- **வயதில்மூத்தமாதரைப்புணரக்கூடாது**
- **பெண்களிடத்தில்மாதத்திற்குஒருமுறைமட்டும்புணர்ச்சியில்ஈடுபடவேண்டும்**
- **4 நாட்களுக்குஎண்ணெய்முழுக்குசெய்யவேண்டும்**

-சித்தமருத்துவாங்கசுருக்கம்

THE MALE REPRODUCTIVE SYSTEM



Male Reproductive System

The functions male reproductive system:

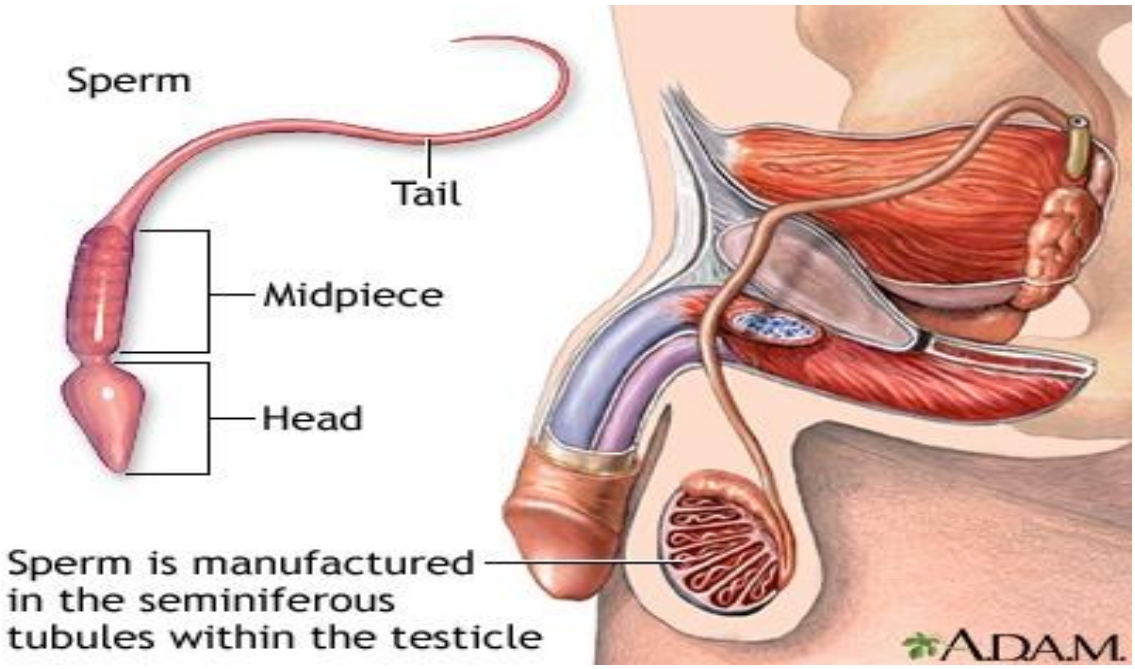
- To produce, maintain, and transport sperm (the male reproductive cells) and protective fluid (semen)
- To discharge sperm within the female reproductive tract during sex
- To produce and secrete male sex hormones responsible for maintaining the male reproductive system.

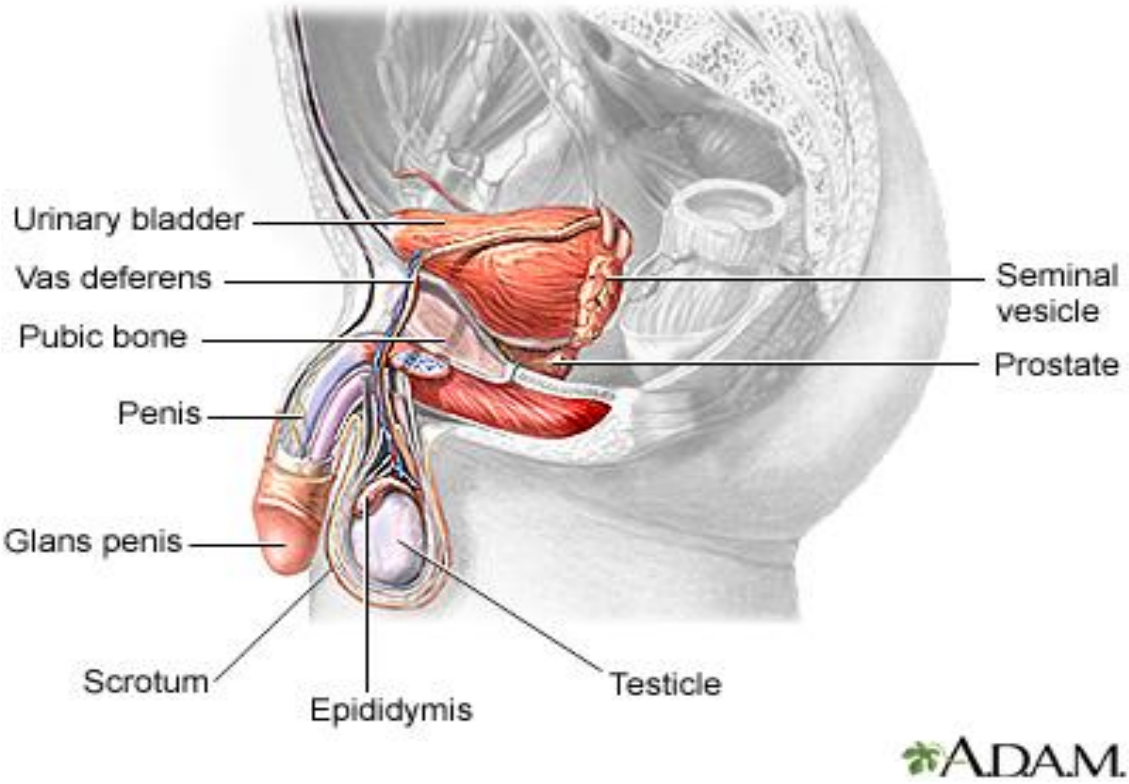
Function of the Male Reproductive System

The entire male reproductive system is dependent on hormones, which are chemicals that regulate the activity of many different types of cells or organs. The primary hormones involved in the male reproductive system are follicle-stimulating hormone, luteinizing hormone, and testosterone.

Follicle-stimulating hormone is necessary for sperm production (spermatogenesis), and luteinizing hormone stimulates the production of testosterone, which is also needed to make sperm. Testosterone is responsible for the development of male characteristics, including muscle mass and strength, fat distribution, bone mass, facial hair growth, voice change, and sex drive.

Semen, which contains sperm (reproductive cells), is expelled (ejaculated) through the end of the penis when the man reaches sexual climax (orgasm). When the penis is erect, the flow of urine is blocked from the urethra, allowing only semen to be ejaculated at orgasm.





Unlike the female reproductive system, most of the male reproductive system is located outside the body. These external structures include the penis, scrotum, and testicles.

Penis:

This is the male organ used in sexual intercourse.

It has three parts: 1. The root 2.The body or shaft 3.The glans.

The root:

It attaches to the wall of the abdomen.

The body or shaft and the glans

It is the cone-shaped part at the end of the penis. The glans, also called the head of the penis, is covered with a loose layer of skin called foreskin. This skin is sometimes removed in a procedure called circumcision. The opening of the urethra, the tube that transports semen and urine, is at the tip of the penis. The penis also contains a number of sensitive nerve endings.

The body of the penis is cylindrical in shape and consists of three circular shaped chambers. These chambers are made up of special, sponge-like tissue. This tissue contains thousands of large spaces that fill with blood when the man is sexually aroused. As the penis fills with blood, it becomes rigid and erect, which allows for penetration during sexual intercourse. The skin of the penis is loose and elastic to accommodate changes in penis size during an erection.

The internal organs of the male reproductive system, are called as accessory organs which includes the following:

Epididymis:

The epididymis is a long, coiled tube that rests on the backside of each testicle. It transports and stores sperm cells that are produced in the testes. The job of the epididymis is to bring the sperm to attain maturity, since the sperms that emerge from the testes are immature and incapable of fertilization. During sexual arousal, some contractions force the sperm into the vas deferens.

Vas deferens:

The vas deferens is a long, muscular tube that travels from the epididymis into the pelvic cavity, just behind the bladder. The vas deferens transports mature sperm to the urethra. It is the tube which carries urine or sperm out of the body, in preparation for ejaculation.

Ejaculatory ducts:

These are formed by the fusion of the vas deferens and the seminal vesicles (see below). The ejaculatory ducts empty into the urethra.

Urethra:

The urethra is the tube that carries urine from the bladder to out of the body. In males, it has the additional function of ejaculating semen when the man reaches orgasm. When the penis is erect during sex, the flow of urine is blocked from the urethra, allowing only semen to be ejaculated at orgasm.

Seminal vesicles:

The seminal vesicles are sac-like pouches that attach to the vas deferens near the base of the bladder. The seminal vesicles produce a sugar-rich fluid (fructose) that provides sperm with a source of energy to help them move. The fluid of the seminal vesicles makes up most of the volume of a man's ejaculatory fluid, or ejaculate.

Prostate gland:

The prostate gland is a walnut-sized structure that is located below the urinary bladder in front of the rectum. The prostate gland contributes additional fluid to the ejaculate. Prostate fluids also help to nourish the sperm. The urethra, which carries the ejaculate to be expelled , runs through the center of the prostate gland.

Bulbourethral glands:

Also called Cowper's glands, these are pea-sized structures located on the sides of the urethra just below the prostate gland. These glands produce a clear, slippery fluid that empties directly into the urethra. This fluid serves to lubricate the urethra and to neutralize any acidity that may be present due to residual drops of urine in the urethra.

Scrotum:

This is the loose pouch-like sac of skin that hangs behind and below the penis. It contains the testicles (also called testes), as well as many nerves and blood vessels. The scrotum acts as a "climate control system" for the testes. For normal sperm development, the testes must be at a temperature slightly cooler than body temperature. Special muscles in the wall of the scrotum allow it to contract and relax, moving the testicles closer to the body for warmth or farther away from the body to cool the temperature.

Testicles (testes):

These are oval organs about the size of large olives that lie in the scrotum, secured at either end by a structure called the spermatic cord. Most men have two testes. The testes are responsible for making testosterone, the primary male sex hormone, and for generating sperm. Within the testes are coiled masses of tubes called seminiferous tubules. These tubes are responsible for producing sperm cells.

SpermSperm are made in hundreds of microscopic tubes, known as seminiferous tubules, which make up most of the testicles.

- Surrounding these tubules are clumps of tissue containing Leydig cells, which produce testosterone when stimulated by luteinizing hormone (LH).
- Sperm Development. The life cycle of sperm takes about 74 days:
- Sperm in the begining partially embedded in nurturing Sertoli cells, which are located in the lower parts of the seminiferous tubules.

As they mature move along, and are stored in the upper part of the seminiferous tubules. Young sperm cells are known as spermatids.

When the sperm has completed the development of its head and tail, it is released from the cell into the epididymis. This C-shaped tube is 1/300 of an inch in diameter and about 20 feet long. It loops back and forth on itself within a space that is only about one and a half inches long. The sperm's journey through the epididymis takes about 3 weeks.

The fluid in which the sperm is transported contains sugar in the form of fructose, which provides energy as the sperm matures. In the early stages of its passage, the sperm cannot swim in a forward direction and can only vibrate its tail weakly. By the time the sperm reaches the end of the epididymis, however, it matures and looks like a microscopic squirming tadpole.

At maturity, each healthy sperm consists of a head that contains the man's genetic material (his DNA) and a tail that lashes back and forth at great speed to propel the head forward at about four times its own length every second. The ability of a sperm to move forward rapidly and straight is probably the most significant determinant of male fertility.

Ejaculation. When a man experiences sexual excitement, nerves stimulate the muscles in the epididymis to contract, which forces the sperm out through the penis:

After being produced in the testicle, the sperm first pass through the epididymis and then into one of two rigid and wire-like muscular channels, called the vasa deferentia. (A single member of this pair of channels is called a vas deferens.)

Muscle contractions in the vas deferens from sexual activity propel the sperm along past the seminal vesicles. These are clusters of tissue that contribute fluid, called seminal fluid, to the sperm. The vas deferens also collects fluid from the nearby prostate gland. This mixture of various fluids and sperm is the semen.

Each vas deferens then joins together to form the ejaculatory duct. This duct, which now contains the sperm-containing semen, passes down through the urethra. (The urethra is the same channel in the penis through which a man urinates, but during orgasm, muscles close off the bladder so that urine cannot enter the urethra.) The semen is forced through the urethra during ejaculation, the final stage of orgasm when the sperm is literally shot out of the penis.

Sperm Abnormalities

Sperm abnormalities can be caused by a range of factors, including congenital birth defects, disease, chemical exposure, and lifestyle habits. In many cases, the causes of sperm abnormalities are unknown.

Sperm abnormalities are categorized by whether they affect sperm count, sperm movement, or sperm shape. They include:

Low Sperm Count (Oligospermia)

Sperm count of less than 20 million/mL is considered as Azoospermia refers to the complete absence of sperm cells in the ejaculate. Partial obstruction anywhere in the long passages through which sperm pass can reduce sperm counts. Sperm count varies widely over time, and temporary low counts are common. A single test that reports a low count may not be a representative result.

Poor Sperm Motility (Asthenospermia)

Sperm motility is the sperm's ability to move. If movement is slow or not in a straight line, the sperm have difficulty invading the cervical mucus or penetrating the hard-outer shell of the egg. If 60% or more of sperm have normal motility, the sperm is said to be average in quality. If less than 40% of sperm are able to move in a straight line, the condition is considered abnormal. Sperm that move sluggishly may have genetic or other defects that render them incapable of fertilizing the egg. Poor sperm motility may be associated with DNA fragmentation and may increase the risk for passing on genetic diseases.

Abnormal Sperm Morphology (Teratospermia)

Morphology refers to shape and structure. Abnormally shaped sperm cannot fertilize an egg. About 60% of the sperm should be normal in size and shape for adequate fertility. The perfect sperm structure is an oval head and long tail.

In addition to providing the fluid that transports the sperm, semen also has other benefits:

It provides a very short-lived alkaline environment to protect sperm from the harsh acidity of the female vagina. (If the sperm do not reach the woman's cervix within several hours, the semen itself becomes toxic to sperm and they die.)

It contains a gelatin-like substance that prevents it from draining from the vagina too quickly.

It contains sugar in the form of fructose to provide instant energy for sperm locomotion.

The sperm's passage to the egg is a difficult journey. Semen provides the pathway for the sperm to reach the egg.

Usually about 100 - 300 million sperm are delivered into the ejaculate at any given time. Even under normal conditions only about 15% of these millions of sperm are strong enough to fertilize an egg.

After the stress of ejaculation, only about 400 sperm survive the orgasm to continue the journey.

Out of this number, only about 40 sperm survive the challenges posed by the semen and the environment of the vagina to reach the vicinity of the egg. Normally, the cervical mucus forms an impenetrable barrier to sperm. However, when a woman ovulates (releases her egg, the oocyte), the mucous lining thins to allow sperm penetration.

Sperm that manage to reach the mucus lining in the woman's cervix (the lower part of her uterus) must survive about four more days to reach the woman's fallopian tubes. (Here, the egg is positioned for fertilization for only 12 hours each month.)

The few remaining sperm that penetrate the cervical mucus and are able to reach the fallopian tubes become capacitated.

Capacitation is a one-time explosion of energy that completes the sperm's journey. It boosts the motion of the sperm and triggers the actions of the acrosome, a membrane that covers the head of the sperm and resembles a warhead. The acrosome is dissolved, and enzymes contained within it are released to allow the sperm to drill a hole through the tough outer coating of the egg.

In the end, only one sperm gets through to fertilize the egg

Testosterone

A testosterone test checks the level of this male hormone (androgen) in the blood. Testosterone affects sexual features and development. In men, it is made in large amounts by the testicles. In both men and women, testosterone is made in small amounts by the adrenal glands; and, in women, by the ovaries.

The pituitary gland controls the level of testosterone in the body. When the testosterone level is low, the pituitary gland releases a hormone called luteinizing hormone (LH). This hormone tells the testicles to make more testosterone.

Before puberty, the testosterone level in boys is normally low. Testosterone increases during puberty. This causes boys to develop a deeper voice, get bigger muscles, make sperm, and get facial and body hair. The level of testosterone is the highest around age 40, then gradually becomes less in older men.

In women, the ovaries account for half of the testosterone in the body. Women have a much smaller amount of testosterone in their bodies compared to men. But testosterone plays an important role throughout the body in both men and women. It affects the brain, bone and muscle mass, fat distribution, the vascular system, energy levels, genital tissues, and sexual functioning.

Most of the testosterone in the blood is bound to a protein called sex hormone binding globulin (SHBG). Testosterone that is not bound ("free") can also be checked if a man or a woman is having sexual problems.

Significance of testosterone:

- A low amount of testosterone can lead to low sperm counts.
- A low level of testosterone may lower a man's sex drive or not allow him to have an erection (erectile dysfunction).
- See whether a high level of testosterone is causing a boy younger than age 10 to have early signs of puberty.
- Check a decreased sex drive in a woman. This may be due to the level of testosterone in her body.
- Find out why a woman is developing male features, such as excessive facial and body hair (hirsutism) and a deep voice.
- Find out why a woman is having irregular menstrual periods.
- See if testosterone-lowering medicines are working in a man with advancedprostate cancer.
- Find the cause of osteoporosis in a man.

A testosterone test checks the level of androgen (male sex hormone) in the blood.

Normal

The normal values listed here-called a reference range-are just a guide. These ranges vary from lab to lab, and your lab may have a different range for what's normal.

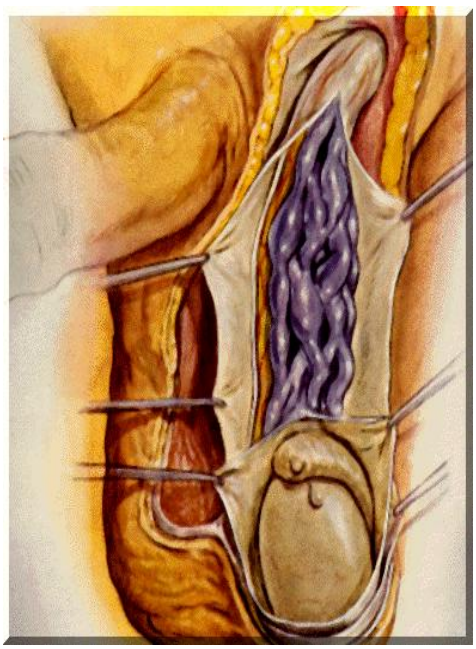
Table: 1

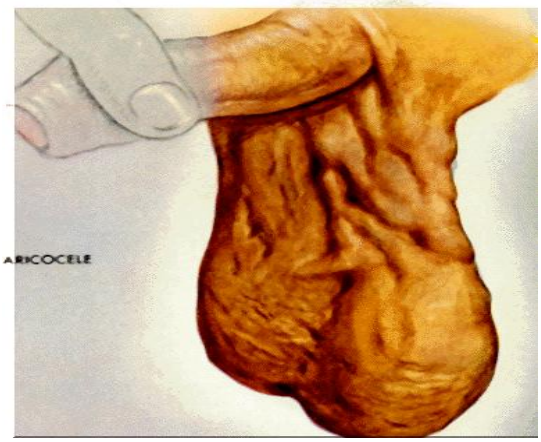
Total testosterone	
Men	270-1070 ng/dL (9-38 nmol/L)
Women	15-70 ng/dL (0.52-2.4 nmol/L)
Children	2-20 ng/dL or 0.07-0.7 nmol/L

The testosterone level for a postmenopausal woman is about half the normal level for a healthy, nonpregnant woman. And a pregnant woman will have 3 to 4 times the amount of testosterone compared to a healthy, nonpregnant woman.

Table: 2

Free testosterone	
Men	50-210 pg/mL (174-729 pmol/L)
Women	1.0-8.5 pg/mL (3.5-29.5 pmol/L)





The etiologic factors in male infertility continue to be debated and there is incomplete knowledge about its pathophysiology.

A varicocele develops when the one way valves in these spermatic veins are damaged causing an abnormal back flow of blood from the abdomen into the scrotum creating a hostile environment for sperm development. Varicocoeles may cause reduced sperm count and abnormal sperm morphology which cause infertility. Variococles can usually be diagnosed by a physical examination of the scrotum which can be aided by the Doppler stethoscope and scrotal ultrasound. Varicocoele can be treated in many ways but the most successful treatments involve corrective surgery.

INVESTIGATION

1.Semen sample

A semen sample is collected by masturbation. Patient is adviced to urinate and then wash and rinse their hands and penis before collecting the semen in a sterile cup. Lubricants or condoms should not be used when collecting the sample. While collect the semen sample at home, be sure to get it to the lab or clinic within 1 hour. Keep the sample at body temperature and out of direct sunlight. The sample cannot be collected by having sexual intercourse and then withdrawing when you ejaculate because vaginal fluid may be mixed with the sperm.

2.Collection of Semen

Patient was asked to avoid any sexual activity that results in ejaculation for 2 to 5 days before a semen analysis. This helps to ensure that sperm count will be at its highest, and it improves the reliability of the test. If possible, do not avoid sexual activity for more than 1 to 2 weeks before this test, because a long period of sexual inactivity can result in less active sperm.

Patient was asked to avoid drinking alcohol for a few days before the test. The most common way to collect semen is by masturbation, directing the semen into a clean sample cup. Do not use a lubricant.

Patient was advised to collect a semen sample during sex by withdrawing their penis from their partner just before ejaculating (coitus interruptus). patient then ejaculate into a clean sample cup. This method can be used after a vasectomy to test for the presence of sperm, but other methods will likely be recommended if you are testing for infertility.

Sperm collection by surgical method:

If sperm cannot be collected by means of masturbation, they are surgically removed from a testicle through a small incision. This method of sperm retrieval is done when there is a blockage that prevents sperm from being ejaculated or when there is a problem with sperm development. To screen for possible genetic problems that could affect offspring, experts recommend that men with little or no sperm in their semen (not due to a blockage) have genetic testing before they proceed with ICSI.

3. Sperm Penetration Tests

Sperm penetration tests were check carried out to whether a man's sperm can move through cervical mucus and the fallopian tubes to join with (fertilize) an egg. This test is usually done when a couple is having trouble becoming pregnant (infertility).

SEMEN ANALYSIS

Volume	**:**	This is a measure of how much semen is present in one ejaculation.
Liquefaction time	:	Semen is a thick gel at the time of ejaculation and normally becomes liquid within 20 minutes after ejaculation. Liquefaction time is a measure of the time taken by the semen to liquefy.
Sperm count	**:**	This is a count of the number of sperm present per milliliter (mL)of semen in one ejaculation.
Sperm morphology	:	This is a measure of the percentage of sperm that have a normal shape.

Sperm motility : This is a measure of the percentage of sperm that can move forward normally. The number of sperm that show normal forward movement in a certain amount of semen can also be measured (motile density).

pH **:** This is a measure of the acidity (low pH) or alkalinity (high pH) of the semen.

White blood cell count **:** White blood cells are not normally present in semen.

Fructose level : This is a measure of the amount of a sugar called fructose in the semen. The fructose provides energy for the sperm.

Significance of Semen Analysis:

A semen analysis is done to determine whether:

- A man has a reproductive problem that is causing infertility.
- A vasectomy has been successful.
- The reversal of a vasectomy has been successful.

Intracytoplasmic Sperm Injection for Infertility

Intracytoplasmic sperm injection (ICSI) is an assisted reproductive technology (ART) used to treat sperm-related infertility problems. ICSI is used to enhance the fertilization phase of in vitro fertilization (IVF) by injecting a single sperm into a mature egg. The fertilized egg is then placed in a woman's uterus or fallopian tube.

4.Antisperm Antibody Test

An antisperm antibody test looks for special proteins (antibodies) that fight against a man's sperm in blood, vaginal fluids, or semen. The test uses a sample of sperm and adds a substance that binds only to affected sperm.

Semen can cause an immune system response in either the man's or woman's body. The antibodies can damage or kill sperm. If a high number of sperm antibodies come into contact with a man's sperm, it may be hard for the sperm to fertilize an egg. The couple has a hard time becoming pregnant. This is called immunologic infertility.

A man can make sperm antibodies when his sperm come into contact with his immune system. This can happen when the testicles are injured or after surgeries (such as a biopsy or vasectomy) or after a prostate gland infection. The testicles normally keep the sperm away from the rest of the body and the immune system.

A woman can have an allergic reaction to her partner's semen and make sperm antibodies. This kind of immune response is not fully understood but may affect fertility. This is a rare cause of infertility.

Significance of Antisperm antibody test

The antisperm antibody test may be done if: A cause for infertility cannot be found. Experts disagree about the usefulness of the test because the result may not change the treatment.

The results from another fertility test, such as the postcoital test, are not clear. An antisperm antibody test looks for special proteins (antibodies) that fight against a man's sperm in blood, vaginal fluids, or semen. The higher the level of antibody-affected sperm found in the semen, the lower the chance of the sperm fertilizing an egg.

Medical causes for Male infertility

Problems with male fertility can be caused by a number of health issues and medical treatments. More than 90% of male infertility cases are due to low sperm counts, poor sperm quality, or both. The remaining cases of male infertility can be caused by a number of factors including anatomical problems, hormonal imbalances, and genetic defects

Varicocele: A varicocele is a swelling of the veins that drain the testicle. It's a common cause of male infertility. This may prevent normal cooling of the testicle, leading to reduced sperm count and fewer moving sperm.

Infection:

Some infections can interfere with sperm production or sperm health, or can cause scarring that blocks the passage of sperm. These include some sexually transmitted infections, including chlamydia and gonorrhea; inflammation of the prostate (prostatitis); and inflamed testicles due to mumps (mumps orchitis).

Ejaculation issues:

Retrograde ejaculation occurs when semen enters the bladder during orgasm instead of emerging out the tip of the penis. Various health conditions can cause retrograde ejaculation, including diabetes, spinal injuries, medications, and surgery of the bladder, prostate or urethra. Some men with spinal cord injuries or certain diseases can't ejaculate semen, even though they still produce sperm.

Antibodies that attack sperm:

Anti-sperm antibodies are immune system cells that mistakenly identify sperm as harmful invaders and attempt to eliminate them.

Tumors:

Cancers and nonmalignant tumors can affect the male reproductive organs directly or can affect the glands that release hormones related to reproduction, such as the pituitary gland. In some cases, surgery, radiation or chemotherapy to treat tumors can affect male fertility.

Undescended testicles:

In some males, during fetal development one or both testicles fail to descend from the abdomen into the sac that normally contains the testicles (scrotum). Decreased fertility is more likely in men who have had this condition.

Hormone imbalances:

Infertility can result from disorders of the testicles themselves or an abnormality affecting other hormonal systems including the hypothalamus, pituitary, thyroid and adrenal glands. Low testosterone (male hypogonadism) and other hormonal problems have a number of possible underlying causes.

Sperm duct defects:

The tubes that carry sperm (sperm ducts) can be damaged by illness or injury. Some men experience blockage in the part of the testicle that stores sperm (epididymis) or a blockage of one or both of the tubes that carry sperm out of the testicles. Men with cystic fibrosis and some other inherited conditions may be born without sperm ducts altogether.

Chromosome defects:

Inherited disorders such as Klinefelter's syndrome — in which a male is born with two X chromosomes and one Y chromosome (instead of one X and one Y) — cause abnormal development of the male reproductive organs. Other genetic syndromes associated with infertility include cystic fibrosis, Kallmann's syndrome, Young's syndrome and Kartigener syndrome.

Problems with sexual intercourse:

These can include trouble keeping or maintaining an erection sufficient for sex (erectile dysfunction), premature ejaculation, painful intercourse, anatomical abnormalities such as having a urethral opening beneath the penis (hypospadias), or psychological or relationship problems that interfere with sex.

Celiac disease:

A digestive disorder caused by sensitivity to gluten, celiac disease can cause male infertility. Fertility may improve after adopting a gluten-free diet.

Certain medications:

Testosterone replacement therapy, long-term anabolic steroid use, cancer medications (chemotherapy), certain antifungal medications, some ulcer drugs and certain other medications can impair sperm production and decrease male fertility.

Environmental causes:

Over exposure to certain environmental elements such as heat, toxins and chemicals canreduce sperm production or sperm function. Specific causes include:

Industrial chemicals:

Extended exposure to benzenes, toluene, xylene, pesticides, herbicides, organic solvents, painting materials and lead may contribute to low sperm counts.

Heavy metal exposure:

Exposure to lead or other heavy metals also may cause infertility.

Radiation or X-rays:

Exposure to radiation can reduce sperm production, though it will often eventually return to normal. With high doses of radiation, sperm production can be permanently reduced.

Exposure to Heat:

Frequent use of saunas or hot tubs may temporarily lower your sperm count. Sitting for long periods, wearing tight clothing or working on a laptop computer for long stretches of time also may increase the temperature in your scrotum and slightly reduce sperm production. The type of underwear you wear is unlikely to make a significant difference in male fertility

HEALTH, LIFESTYLE AND OTHER CAUSES

Some other causes of male infertility include:

Illegal drug use: Anabolic steroids taken to stimulate muscle strength and growth can cause the testicles to shrink and sperm production to decrease. Use of cocaine or marijuana may temporarily reduce the number and quality of your sperm as well.

Alcohol Use:

Drinking alcohol can lower testosterone levels, cause erectile dysfunction and decrease sperm production. Liver disease caused by excessive drinking also may lead to fertility problems.

Occupation:

Certain occupations can increase your risk of infertility, including those associated with extended use of computers or video display monitors, shift work, and work-related stress.

Tobacco smoking:

Men who smoke may have a lower sperm count than do those who don't smoke. Secondhand smoke also may affect male fertility.

Emotional stress:

Stress can interfere with certain hormones needed to produce sperm. Severe or prolonged emotional stress, including problems with fertility, can affect your sperm count.

Weight:

Obesity can cause hormone changes that reduce male fertility.

Prolonged bicycling:

Prolonged bicycling is another possible cause of reduced fertility due to overheating the testicles. In some cases, bicycle seat pressure on the area behind the testicles (perineum) can cause numbness in the penis and erectile hormonal deficiencies.

Hypogonadism is the general name for a severe deficiency in gonadotropin-releasing hormone (GnRH), the primary hormone that signals the process leading to the release of testosterone and other important reproductive hormones. Low levels of testosterone from any cause may result in defective sperm production.

PSYCHOLOGICAL/PHYSICAL/BEHAVIORAL PROBLEMS

Several sexual problems both psychological and physical in nature. It is difficult to separate the physiological and physical components exist that can affect male fertility.

Erectile dysfunction(ED):

ED is the result of a single, or more commonly a combination of multiple factors. In the past, ED was thought to be the result of psychological problems, but new research indicates that 90 percent of cases are organic in nature. However, most men who suffer from ED have a secondary psychological problem that can worsen the situation like performance anxiety, guilt, and low self-esteem.

Common causes of impotence include:

Diabetes, high blood pressure, heart and vascular disease, stress, hormone problems, pelvic surgery, trauma, venous leak.

Premature Ejaculation:

It is defined as an inability to control the ejaculatory response for at least thirty seconds following penetration. Premature ejaculation becomes a fertility problem when ejaculation occurs before a man is able to fully insert his penis into his partner's vagina. Premature ejaculation can be overcome by artificial insemination or by using a behavioral modification technique called the "squeeze technique" which desensitizes the penis.

Ejaculatory Incompetence:

This rare psychological condition prevents men from ejaculating during sexual intercourse even though they can ejaculate normally through masturbation. This condition sometimes responds well to behavioral therapy; if this technique does not work, artificial insemination can be employed using an ejaculate from masturbation.

RISK FACTORS REGARDING MALE INFERTILITY

A number of risk factors are linked to male infertility. They include:

- Smoking tobacco
- Using alcohol
- Using certain illegal drugs
- Being overweight
- Having certain past or present infections
- Being exposed to toxins
- Overheating the testicles
- Having a prior vasectomy or vasectomy reversal
- Being born with a fertility disorder or having a blood relative with a fertility disorder
- Having certain medical conditions, including tumors and chronic illnesses
- Taking certain medications or undergoing medical treatments, such surgery or radiation used for treating cancer
- Performing certain prolonged activities such as bicycling or horseback riding, especially on a hard seat or poorly adjusted bicycle

Complications of Male infertility

Infertility can be stressful for both male and female. Complications can include:

- Surgery or other procedures to treat an underlying cause of low sperm count or other reproductive problems
- Expensive and involved reproductive techniques such as in vitro fertilization
- Stress and relationship difficulties related to the inability to have a child

LIFESTYLE CHANGES

Timing and Monitoring Sexual Activity for Best Results

Both male and female hormone levels fluctuate according to the time of day, and they also vary from day to day and month to month. Some timing tips might be helpful.

Fertility and Seasonal Changes.

Some studies have reported higher sperm counts in the winter than in the summer. For women, fertility rates as measured by treatment success are highest in months when days are longest.

Monitoring Basal Body Temperature.

To determine the most likely time of ovulation and therefore the time of fertility, a woman should take her body temperature, called her basal body temperature. This is the body's temperature as it rises and falls in accord with hormonal fluctuations.

By studying the temperature patterns after a few months, couples can begin to anticipate ovulation and plan their sexual activity accordingly.

Frequency of Intercourse.

It is not clear how often a couple should have intercourse in order to conceive. Some doctors think that having sex more than 2 days a week adds no benefits. In addition, frequent sexual activity lowers sperm count per ejaculation. Some studies have indicated, however, that having intercourse every day, or even several times a day, before and during ovulation, improves pregnancy rates. Although sperm count per ejaculation is low, a constantly replenished semen supply is more likely to result in a fertilized egg.

Dietary Considerations:

Everyone should eat a healthy diet rich in fresh fruits, vegetables, and whole grains. Replace animal fats with monounsaturated oils, such as olive oil. Certain specific nutrients and vitamins have been studied for their effects on male infertility and sperm health. They include antioxidant vitamins (vitamin C, vitamin E) and the dietary supplements L-carnitine and L-acetylcarnitine. To date, there is no conclusive evidence that they are effective.

NUTRITIONAL CONSIDERATIONS

Vitamin c and other Anti- oxidants

Free radical or oxidative damage to sperm is thought to be responsible for many cases of idiopathic oligospermia, with high levels of free radicals found in the semen of 40% infertile men. Three factors combine to render sperm particularly susceptible to free radical damage.

- A high membrane concentration of polysaturated fatty acids
- Active generation of free radicals

A lack of defensive enzymes.

The health of the sperm critically dependent upon antioxidants. Although most free radicals are produced during normal metabolic processes, the environment contributes greatly to the free radical load. Men exposed to increased levels of source of free radicals are much more likely to have abnormal sperm and sperm counts.

Sperm extremely sensitive to free radicals because they are so dependent upon the integrity and fluidity of their cell membrane for proper function. Without proper membrane fluidity, enzymes are activated, which can lead to impaired motility, abnormal structure loss of viability and ultimately death of sperm. The major determinant of membrane fluidity is the concentration of polyunsaturated fatty acids, particularly omega-3 fatty acids which are very susceptible to free radical damage. The sperm have a relative lack of super oxide dismutase and catalase which can prevent oxidative damage.

A common source of oxide is cigarette smoking, which is associated with decreased sperm counts and sperm motility as well as increased frequency of abnormal sperm. Increase in environmental pollution, is thought to be a major contributor to the decreased in sperm counts seen in many industrialized nations. Anti oxidants such as vitamin C, beta carotene, selenium and vitamin E have been shown to be very important in protecting sperm against damage. Vitamin C plays a vital role in protecting the sperm's genetic material (DNA) from damage. Ascorbic acid levels are much higher in seminal fluid compared with other body fluids. When dietary vitamin C was reduced from 250 to 5mg/ day in healty human subjects, the seminal fluid ascorbic acid decreased by 50% and the number of sperm with damage of DNA increased by 91%.

It is well documented that cigarette smoking greatly reduces vitamin C levels throughout the body. Vitamin E has been shown to play an essential role in inhibiting free radical damage to the unsaturated fatty acids of the sperm membrane. Vitamin E enhances the ability of sperm to fertilize an egg in test tubes.

Fats and oils

Saturated fats, hydrogenated oils, trans-fatty acids, cotton seed, coconut and palm oil should be avoided. Coconut and palm oils are primarily saturated fat, while cotton seed may contain toxic residues, due to heavy spraying of cotton and its high levels of gossypol, a substance known to inhibit the sperm function. Infact, gossypol is being investigated as the "male birth control pill". Its use as an antifertility agent began after studies demonstrated that men who had used crude cotton seed oil as their cooking oil were shown to have low sperm counts followed by total testicular failure. Excessive consumption of saturated fats combined with inadequate intake of essential fatty acids changes the fatty acid composition of sperm membranes, thus decreasing fluidity and interfering with sperm motility.

The patient must be informed to read food labels carefully and avoid all sources of cotton seed oil and other damaging oils. While the in take of saturated and hydrogenated fats must be eliminated, the intake of polyunsaturated oils should be increased. These oils function in all aspects of sexual function including sperm formation and activity much lower in infertile men with low sperm counts, including that a low zinc status may be the contributing factor to the infertility. Zinc is found in whole grains, legumes, nuts and seeds.

Vitamin B12

Vitamin B12 is involved in cellular replication. A deficiency of vitamin B12 leads to reduced sperm counts and sperm motility.

Arginine

The amino acids arginine is required for the replication of cells, making it essential in sperm formation.

Carnitine

Carnitine is essential in the transport of fatty acids in to the mitochondria. A deficiency of carnitine results in a decrease in fatty acid concentrations in the mitochondria and reduced energy production. Carnitine concentrations are extremely high in the epididymis and sperm, suggesting a role for carnitine in male reproductive function. The epididymis derives the majority of its energy requirements from fatty acids, as do the sperm, during transport through the epididymis. after the ejaculation, the motility of sperm correlates directly with carnitine content.

The higher the carnitine content, the more motile are the sperm. Supplementing th diet with L- carnitine may be useful in restoring male fertility

PROTOCOL

TITLE:

AN OPEN CLINICAL TRAIL OF A SIDDHA HERBAL FORMULATION "THATHU VIRTHI KULIGAI" IN THE TREATMENT OF "AAN MALADU" (MALE INFERTILITY)

REG NO: **DATE OF SUBMISSION:**

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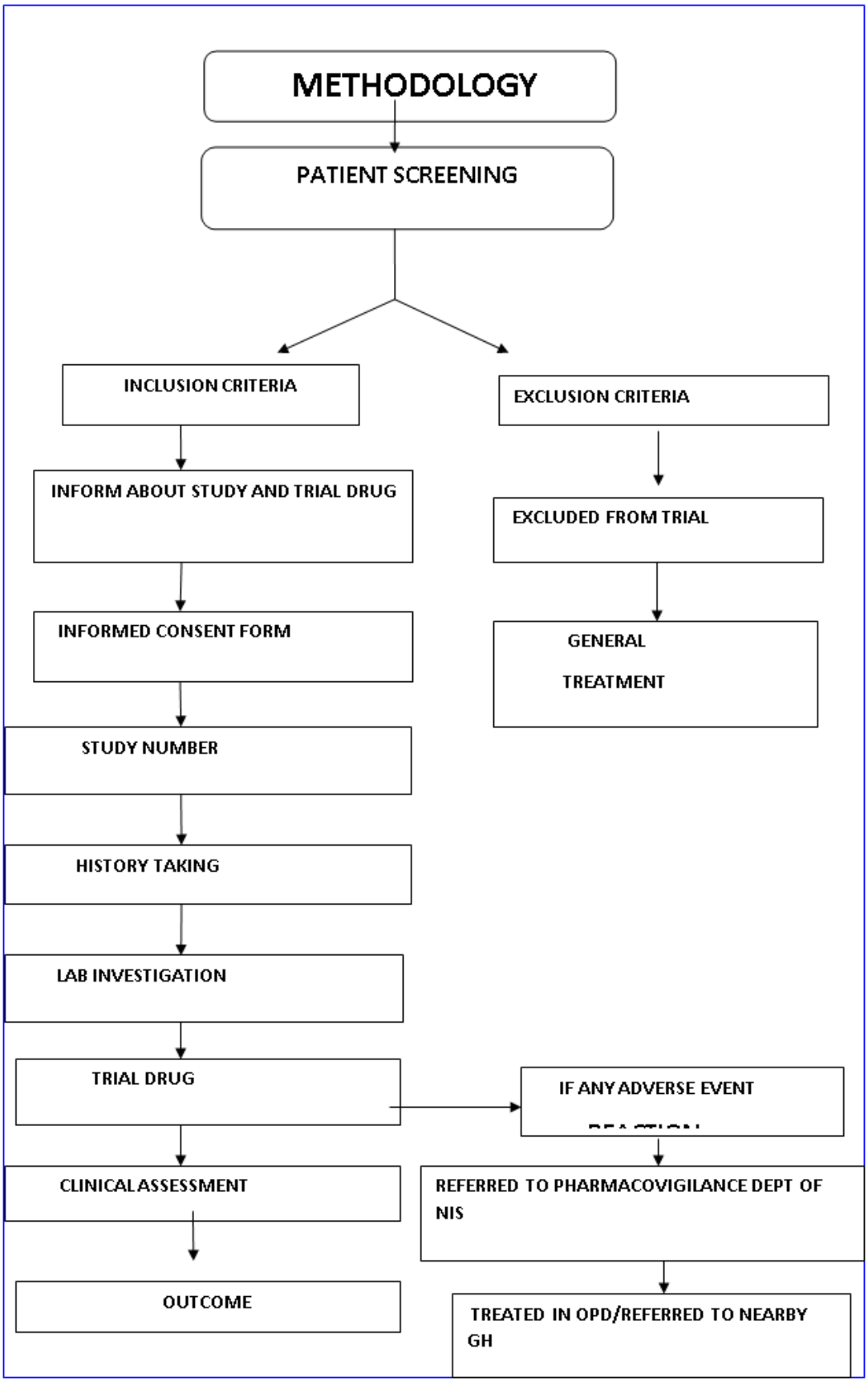

METHODOLOGY
PATIENT SCREENING
INCLUSION CRITERIA
EXCLUSION CRITERIA
INFORM ABOUT STUDY AND TRIAL DRUG
EXCLUDED FROM TRIAL
INFORMED CONSENT FORM
GENERAL
TREATMENT
STUDY NUMBER
HISTORY TAKING
LAB INVESTIGATION
TRIAL DRUG
IF ANY ADVERSE EVENT
CLINICAL ASSESSMENT
REFERRED TO PHARMACOVIGILANCE DEPT OF NIS
OUTCOME
TREATED IN OPD/REFERRED TO NEARBY GH

BACK GROUND:

In 20th century usage of herbal based medicinal therapy gained importance and found their place in 40% of prescription because of their lesser side effects compared with other modern drugs. The usage of medicinal plant products in the form of plant extracts and their active components etc

Yugi muni had done a lot of contribution to the siddha system, includes the classification of disease into 4448. AAN MALADU is one among them. According to Yugi muni in Aanmaladu the semen exhibits the following characters such as absence of sweetness, buoyancy on water. He further explained the character of urine in Aanmaldu as froth in urine and symptoms like absence of virility. Sukkilam one among the seven udalthathukkal is affected in Aanmaladu.

Infertility bears a social stigma. The incidence of infertility is follows males - 40% females- 40% and both sex -20%. Aanmaladu is a disease known as male Infertility in modern science. Most cases of male infertility are due to an abnormal sperm, abnormal sperm count and low sperm motility. Infertility is the inability of a sexually active, non-contraception couple to achieve pregnancy in one year. As per WHO guidelines a report with count less than 15 million / ml is oligospermia. There was a time when infertility was only limited to women. In present scenario male infertility is blamed in 50 % of cases where couples could not conceive naturally. Male infertility is a global problem in the field of reproductive health. Most of the cases hailing from IT back ground, chemical industry, oil refineraries, other than occupation viral infection during childhood (ex mumps) endocrine disorder, trauma(testes) low economic standards, are predispose to increase the rate of infertility.

The research study entitled Aanmaldu (Male infertility) mainly focus on outcome of qualitative and quantitative analysis of semen in oligospermia patients with the trial drug Thathuvirthikuligai. Thathuvirthikuligai is a poly herbal Siddha formulation.

Neermullivirai [hygrophilla Auriculata], poonaikalivithuchooranam [mucunapruriens], nillapanaikilanguchooranam [curculigoorchinoids] thaneervittankilanguchooranam [Asparagus resimosus], karuvelampattai poo, pisin

[acacia nilotica], lime juice [citroslimon] and red illaneer are the ingridients present in this formulation. Spermatogenic, diuretic and aphrodisiac action of ingridients present in this formulation were documented in various research articles.

Since the trial medicines is yet to be documented for its efficacy in Aanmaladu.

OBJECTIVE:

Primary objective:

To evaluate the therapeutic efficacy of siddha formulation "Thathuvirthikuligai" in the treatment of AAN MALADU (male infertility)

Secondary objective:

To study and siddha parameter such as cofactors such as, occupations, socio economic status, dietary and influence.etc

STUDY DESIGN & CONDUCT OF STUDY:

Study type : An open clinical trial
Study place : OPD of Ayothidasspandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47.
Study period : 12 months
Sample size : 40 patients

TREATMENT:

MEDICINE NAME:

"THATHU VIRUTHI KULIGAI"

Ref : NOIKALUKU SIDDHA PARIKARAM

Author: Dr.M. SHANMUGAVELU H.P.I.M: 2st Edition, pg no 165

DOSAGE : One maathirai(325mg) twice a day After food
ADJUVANT : Cow's Milk
DURATION : 48 days
ROUTE OF DRUG ADMINISTRATION: Oral route

STANDARD OPERATING PROCEDURE OF THE TRIAL DRUG - "THATHU VIRTHI KULIGAI"

SOURCE OF RAW DRUGS:

The required raw drugs for the preparation of Thathuviruthikuligai will be purchased from a well reputed country shop. The raw drugs will be authenticated by the Asst. Prof of medicinal botany at NIS. Then the raw drugs will be purified as mentioned in siddha literature. The medicine is prepared in Gunapadam lab of National Institute of Siddha.

REQUIRED RAW DRUGS:

1. Neermullivirai [Hygrophilaauriculata], Linn Dc)
2. Poonaikallivithuchooranam [mucunapruriens], Linn)
3. Thanneervittankizhangu (Asparagus *racemosus*, Wild)
4. Nillapanaikilanguchooranam [curculio orchinoids], Dc)
5. Karuvellampattai flowers, pisin [acacia Nilotica], Linn)
6. Lime fruit juice [citrus limon] and
   Red illaneer

METHOD OF PURIFICATION:

1. POONAI KALI (Mucuna*pruiens,* Linn Dc)
   a. Part used: Seed
   b. Fry the seeds in a mud vessel.
2. NEERMULLI [Hygrophila*auriculata*],
   a. Part used: Seed
   b. Fry the seeds in a mud vessel.
3. THANEER VITTAN (Asparagus *racemosus,* Wild.)
   a. Part used: Root tuber
   b. Wash the root tuber with running water and dry it.
4. NILAPPANAI KIZHANGU
   a. Part used: Root tuber
   b. Wash the root tuber with running water and dry it.

5. KARUVEL-
    a. Part used: Flower, leaves and gum
    b. Dry all the above in shade and powder it.

PREPARATION:

All these five ingridients are soaked in Lime Fruit Juice for a day, then rubbed in a kalvam with the same lime juice for 2or3 days then allowed to dry, again rubbed with Red illaneer for another 2or 3days and till it is waxy consistency. it is rounded in to pills of 5 grains or about the size of illanthaivirai and dried in the shade.

DRUG STORAGE:

The trial drug "THATHU VIRUTHI KULIGAI" (internal) is stored in clean and dry wide mouthed glass bottles.

DISPENSING:

The prepared drug will be dispensed in sachets (14 pills in each) once in 7 days for 48 days.

SUBJECT SELECTION:

As and when patients reporting at OPD of AyothidassPandithar Hospital with symptoms mentioned in inclusion criteria will be subjected to screening test & documentation will be done by using screening proforma.

INCLUSION CRITERIA:

1. Male infertile
2. Age 21- 45 year
3. Maritial status - more than 1 year
4. Sperm count $\leq$ 40 million / ejaculation
5. Motility less than $\leq$ 50 %
6. Patients who are willing to sign the informed consent stating that he will continuously stick to the treatment during 48days but can opt out of the trial of his own conscious discretion.
7. Patients who are willing to give specimen of blood, urine and semen before and after treatment.

EXCLUSION CRITERIA

1. Azoospermia
2. Hydrocele
3. Diabetes mellitus
4. Hypertension
5. Endocrine disorders[hypothyroidism&hyperthyroidism]
6. Cardiac diseases
7. VDRL & STD
8. Inguinal Hernia
9. Renal diseases
10. Varicose veins

WITHDRAWAL CRITERIA

1. Intolerance to the drug & development of adverse reactions during drug trial.
2. Poor patient compliance & defaulters.
3. Patient turned unwilling to continue in the course of clinical trial.
4. Increase in severity of symptoms.

TEST & ASSESSMENTS

A.CLINICAL ASSESSMENT - SIDDHA ASSESSMENT

B. ROUTINE INVESTIGATION

C. SPECIFIC INVESTIGATION

A. CLINICAL ASSESSMENT (5

- Premature ejaculation
- Nocturnal emission
- Erectile dysfunction
- Painful coitus
- Painful micturition

SIDDHA ASSESSMENT

1.Thinai:

- Kurinchi (hill areas)
- Mullai (forest)
- Marutham (fertile land)
- Neidhal (coastal area)
- Palai (desert)

2. ***ParuvaKalam (season)***

- Karkaalam (Aug 18 – Oct 17)
- Koothirkaalm (Oct 18 – Dec 16)
- Munpanikaalm (Dec 17 – Feb 12)
- Pinpanikaalam (Feb 13 – April 13)
- Ilavenilkaalam (April 14 – June 14)
- Muthuvenilkaalam (June 15 – Aug 17)

3. *Poripulankal:*

- Mei (Skin etc)
- Vaai (Tongue etc)
- Kan (Eye etc)
- Mooku (Nose etc)
- Sevi (Ear etc)

4. Ennvagaithervu (Eight types of Examination):

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
  - Neerkuri
  - Neikuri

B. **ROUTINE INVESTIGATION**

- Hb(gm/dl)
- Total WBC Count(cells/cumm)
- DC- Polymorphs (%)
- Lymphocytes (%)
- Eosinophils (%)
- Monocytes (%)
- Basophils (%)
- Total RBC count million cells/cumm)
- ESR (Men 6-12mm/hr Women 7-18 mm/hr)
- B. glucose (mg/dl) F & PP

LIPID PROFILE

- Serum T. cholesterol(mg/dl)-
- HDL cholesterol(mg/dl)-
- LDL cholesterol(mg/dl)-
- VLDL cholesterol(mg/dl)-
- Serum triglycerides (mg/dl)-

KIDNEY FUNCTION TEST

- B. urea(mg/dl)
- S. total creatinine (mg/dl)

LIVER FUNCTION TEST

- S. total bilirubin(mg/dl)
- S. direct bilirubin (mg/dl)
- S. indirect bilirubin (mg/dl)
- SGOT(u/l)
- SGPT (u/l)
- S. alkaline phosphataseu/l)
- S. total protein(g/dl)
- S. albumin (g/dl)
- S. globulin (g/dl)
- S. calcium (mg/dl)
- S. phosphorous (mg/dl)

URINE EXAMINATION

- Albumin
- Sugar (Fasting & post prandial)
- Deposits
- Bile salts
- Bile pigments
- Urobilinogen

Semen analysis –

- Volume
- Colour
- Appearance
- Viscosity
- Liquification time
- Fructose
- Sperm count
- Motility
- Morphology

STUDY ENROLLMENT:

- In this clinical trial patients reporting at NIS OPD with the clinical symptoms of premature ejaculation, Nocturnal emission, Erectile dysfunction, Painful coitus, Painful micturition were examined clinically for enrolling in the study based on the inclusion and exclusion criteria.
- The patients in this study were informed (Form-V) about the objective of the study, trial drug, possible outcomes in their own language and terms understandable to them.
- After ascertaining the patient's willingness, informed consent wereobtained in writing from them in the consent form. (Form- VI)
- All these patients were given unique registration card in which patient's registration number of the study, Address, Phone number and Doctors phone number etc. so as to report easily and if any adverse reactions arise.
- Complete clinical history, complaints and duration, examination findings-- all were recorded in the prescribed Proforma in the history and clinical

assessment forms separately. Screening Form- I were filled up; Form –II and Form –III were used for recording the patient's history, clinical examination of symptoms and signs and laboratory investigations respectively.

- Patients were advised to take the trial drug and appropriate dietary advice (Form IV-D) was given according to the patients' perfect understanding.

CONDUCT OF THE STUDY:

The trial drug THATHU VIRUTHI KULIGAI(Internal) was given for 48 days.

Patients were advised to visit the hospital once in 12 days to get the trial drug. At each clinical visit clinical assessment will be done and prognosis was noted.

Laboratory investigations & SEMEN ANALYSIS was done on 0th day & 48 th day of the trial for OP patients.

If any trial patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he was allowed, but defaulters of one week and more were not be allowed to continue and be withdrawn from the study with fresh case being included.

DATA MANAGEMENT

After enrolling the patient in the study, a separate file for each patient were opened and all forms were filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever the study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable forms.

The screening forms were filed separately. The Data recordings will be monitored for completion by HOD and adverse event by Sr. Research Officer (Statistics). All forms were further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

STATISTICAL ANALYSIS:

All collected data will be entered into the computer and manually cross-checked the correctness of the data entry. The clinical symptoms and labarotary investigation of semen will be analyzed by comparing the two point of data (before and after treatment) paired test and chi-square test will be employed to study the efficacy of treatment. Further, the effect of co factors (age, occupation, socio economic status.etc) were be statistically analyzed.

OUTCOME

1. PRIMARY OUT COME

Primary Outcome is mainly assessed by increase in the sperm count and motility %

RESULT	SPERM COUNT & MOTILITY (/ ejaculates)	FROM	TO
GOOD	SPERM COUNT *	≤ 40 million	≥ 60 million
	MOTILITY % #(RM+PM)	≤ 50%	≥ 70 %
MODERATE	SPERM COUNT *	≤ 40 million	> 50 million
	MOTILITY % #(RM+PM)	≤ 50%	≥ 60 %
MILD	SPERM COUNT *	≤ 40 million	40-50 million
	MOTILITY % #(RM+PM)	≤ 50%	> 50 %

NOTE:

* As per 1999 WHO criteria (1) standard value for total number of spermatozoa ≥ 40 million per ejaculates.

* As per 1999 WHO criteria (1) standard value for motility is ≥ 50 % million per ejaculates.

Progressive motility (PM) - ≥ 50 %

Rapid motility (RM) - 25 %

2. SECONDARY OUT COME

Secondary Out Come is mainly assessed by reduce the clinical symptoms.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction. It will be recorded in pharmacovigilence form, and he would be immediately referred to of Pharmacovigilance department of NIS and proper management will be given in OPD of National institute of siddha.

ETHICAL ISSUES

1. Informed consent were obtained from the patient after explaining about the clinical trial in the understandable language to the patient.

2. The data collected from the patient were kept confidentially.
3. After getting the consent of the patient in the consent form they will be enrolled in the study
4. Treatment would be provided free of cost.
5. No other external or internal medicines were used. There will be no infringement on the rights of patient.
6. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, and needles were used under proper sterilization cover.
7. The patients who were excluded (as per exclusion citeria) were given proper treatment at National Institute of Siddha
8. In conditions of treatment failure, adverse reactions, patients were given alternative treatment at the National Institute of Siddha with full care throughout the end of the treatment

ASSESSMENT FORMS

FORM I	SCREENING AND SELECTION PROFORMA
FORM II	CLINICAL RESEARCH FORM
FORM lll	LABORATORY INVESTIGATION ON ENROLLMENT AND CONCLUSION OF TRIAL
FORM IV	DRUG COMPLIANCE FORM
FORM V	PATIENT INFORMATION SHEET
FORM VI	PATIENT CONSENT FORM
FORM VII	WITHDRAWAL FORM / ADVERSE REACTION FORM / PHARMACOVIGILENCE FORM
FORM VIII	DIETARY ADVICE FORM

STANDARD OPERATING PROCEDURE OF THE TRIAL DRUG THATHU VIRUTHI KULIGAI

SOURCE OF RAW DRUGS:

The required raw drugs for the preparation ofThadhuviruthikuligai was purchased from a well reputed country shop. The raw drugs were authenticated by the Asst.Prof of medicinal botany at NIS. Then the raw drugs were purified as mentioned in siddha literature. The medicine was prepared in Gunapadam lab of National Institute of Siddha.

REQUIRED RAW DRUGS:

1.Poonaikalivithai (Mucuna*pruriens,* Linn Dc)
2. Thanneervittankizhangu (Asparagus *racemosus,* Wild)
3. Nelapanaikilangu (Curculigoorchiodes, Linn)
4. Neermulivithai (Hygrophyllaauriculata, Linn)
5. Karuvellampisin (Acacia Arbica Wild)
6. Sevellaneer (Coccus nucifera, Linn)
7. Lemonjuice (Citruslemon)

METHOD OF PURIFICATION:

THADHU VIRUTHI KULIGAI(Internal)

1. Poonaikalivithai (Mucuna*pruiens,* Linn Dc)
    a. Part used: Seed
    b. Fry the seeds in a mud vessel.
2. Thaneervittan (Asparagus *racemosus,* Wild.)
    a. Part used: Root tuber
    b. Wash the root tuber with running water and dry it.
3. Nilapanaikilangu (Curculigoorchinoides, Linn)
    a. Part used: Root tuber
    b. Wash the root tuber with running water and dry it.
4. Neermullividhai (Hygrophyllaauriculata, Linn)
    a. Part used: Seed
    b. Fry the seeds in a mud vessel.

5. Karuvellampisin (Acacia arabica wild)
    a. Part used: Gum & Flower
    b. Dry all the above in shade and powder it.

PREPARATION:

All these five ingridients were soaked in Lime Fruit Juice for a day, then rubbed in a kalvam with the same lime juice for 2or3days then allowed to dry, again rubbed with Red illaneer for another 2or 3days and till it is waxy consistency. It was rounded in to pills of 5 grains or about the size of illanthaivirai[325mg] and dried in shade.

DRUG STORAGE:

The trial drug "THATHU VIRUTHI KULIGAI" (internal)
was stored in clean and dry wide mouthed glass bottles.

DISPENSING:

The prepared drug were dispensed in sachets (14 pills in each) once in 7 days for 45 days.

POONAIKALI

Botanical name **:** *Mucunapruriens*

Family **:** Fabaceae

Plant description:

Twining herbs, branches terete, striate, downy pubescent. Leaves trifoliate, leaves ovate-rhomboid, apprised white-pubescent. Flowers dark purple with yellow shade on the petal in long axillary racemes. Pods curved, prominently s- shape, densely silk pubescent with persistent pale brown or gray irritant bristles, seeds 4-6, orbicular.

Geographical distribution:

World : Cultivated in Tropics

India : *o*ccasionally in damp places, bushes, hedges and ravines throughout India.

Vernacular names : Sanskrit: Atmagupta, hindi: kivach, kan: Turachi- gida, telgu: Dulagondi, Tamil : Poonai kali.

Trade name : Common cowitch

பூனைக்காலி

தழுதாளைநாற் றத்தோடு சாரிரத்தப் போக்கும்
பழுதுபுரி கின்றகரப்பானும் - அழுதேகுந்
தாலமிசை விந்துவுமாஞ் சாற்றற் கரும்பூனைக்
காலி விதையைக் கழறு.

- அகத்தியர் குணவாகடம்

- Taste - Astringent.
- Potency - Moderate.
- Division - Sweet.
- Part used- Seed.
- Action- Nervine tonic, Aphordisiac

Medicinal uses:

- Traditionally in India the seeds of Mucunapruriens are used as a tonic and aphrodisiac for male virility.
- Seeds are highly reputed medicine for curing Parkinson's disease.
- It is used in fracture healing.
- It is used as anti depressant drug.
- The pods are anthelmintic
- The seeds are anti- inflammatory
- The hairs are used as vermifuge

THANNEER VITTAN

Botanical name **:** *Asparagus racemosus***Willd.**

Family **:** Liliaceace

Plant description:

Perennial armed climbing shrub. Roots tuberous. Stem angular. Leaves scaly. cladodes 2-6 in whorl, linear, falcate. Flowers white in racemes. Fruit berry, globose, red when ripe 3-6 seeded.

Geographical distribution:

World : south Asia, China, Malaysia, and Australia.

India : occasional in forests all over India.

Names: sana: satavariGuj: Ekalakanto, Shatavari; Hind: Chatwal, kan: Aheruballi, mal: Shatavalli, Mar: Zatar, Tamil: Kilvari, Catavari; tel: Pilligadallu.

Trade name: Wild Asparagus.

தண்ணீர்விட்டான்

நீரிழிவைப் போக்கும் நெடுநாட்சு ரத்தையெலாம்
ஊரைவிடுத் தோடவு ரைக்குங்காண் - நாரியாரே ! ஆ
வெண்ணீர்பெய் சோமநோய் வெட்டை யணல்தணிக்குந்
தண்ணீர்விட் டான்கிழங்குக் தான்.

- அகத்தியர் குணவாகடம்

- Taste -Sweet.
- Potency - Moderate.
- Division - Sweet.
- Part used- leaves.

Action- Aphrodisiac, Nutritive, Antispasmodic.

Medicinal uses:

- The root is used in indigenous medicine.
- It is considered aphrodisiac and demulcent.
- It is prescribed for increasing the secretion of milk
- The root is used to cure tuberculosis, leprosy, skin diseases, inflammations

NILAPPANAI KIZHANGU

Botanical name **:** *Curculigoorchides,* Linn

Family **:** Hypoxidaceae

Plant description:

It is an herbaceous tuberous perennial with a short or elongate root stock bearing several fleshy lateral roots: Leaves are sessile or petiolate.

Geographical distribution:

World : Mountain grassland, majority from Taiwan.

India : Forests throughout India.

Names : san: Talamuli, hin: kali mooslie, Bengali: talmalu

Trade name: Golden eye grass, Black musli.

- Taste - Sweet
- Potency - Moderate
- Class - sweet
- Action - Aphrodisiac

Medicinal uses:

- It is Rejuventating and aphrodisiac herb.
- It is a sexual tonic.
- It increases Lipido and physical strength in men.
- It promotes sperm count. It stimulates male sex hormone.

NEERMULLI

Botanical name **:** *Hygrophilaauriculata*,Linn
Family : Acanthaceae

Plant description:

It is an herb growing in wet places. A stout herb. Stems fasiculate, subquadrangular, erect,0.6-1.5 m tall, thickened at the nods, hispid with longhairswith axillary spines, Leaves hairy, oblanceolate, in whorls, Flowers purple blue, bilabilate, Fruits capsule.

Geographical distribution:

India : Forests throughout India due to its exploitation.
Names **:** Hygrophila, Temple plant, Marsh barbell, Gokanta.
Trade name **:** Marshbarble
Taste : Sweet
Potencey : Moderate
Class : Sweet
Action : Aphrodisiac

Medicinal uses:

It stimulates the male genital system and is beneficial in the treatment ofsexual debility, premature ejaculation and erectile failure.

The roots and leaves have diuretic properties. It helps in treating urinary cystitis and calculi. The seeds are useful in increasing Libido.

KARUVEL

Botanical name **:** Acacia arabica

Family **:** Mimosaceae

Plant description:

It is a small thorny decididous tree. It can grow upto 20 meters tall. The green grey leaves are alternate and bipinnate. The flowers are yellow cream coloured and grow on spikes just above the thorns.

Geographical distribution:

World **:** It is native to semi-desert regions of sub-sharan Africa, as well as oman, Pakistan.

India : Throughout west costal India.

Names **:** Gum acacia, Gum Arabict tree, sudan gum and sudan gum Arabic.

Trade name **:** Gum acacia.

Taste : Astringent

potency : modrate

class : sweet.

Action **:** Aphrodisiac.

Medicinal uses:

Gum arabica is used to provide a soothing coating over inflammations in the respiratory, alimentary, and urinary tracts.

ILANEER

Botanical name **:** Cocus nucifera

Family **:** Arecacea

Plant description **:** It is a tree. The term coconut can refer to the whole plant or the seed, or the fruit, which is drupe, not a nut. The coconut tree is topped by a crown composed of about 25-30 pinnate feather-like leaves that are bot 6 feet wide and 18 feet long. There are about 200 leafletsin every leaf colored yellow green while mature turns to brown.

Geographical distribution:

World **:** India –Indonesia region.

India : throughout India.

Names **:** Kalpavriksha, Pokokseibuguna, Buko tree.

Trade name **:** coconut tree

Taste **:** Sweet, Astringent,

Potency **:** moderate,

class **:** sweet.

Action **:** Nutritive, demulcent.

Medicinal uses:

- While consuming the flesh of coconut with coconut milk and honey it increases libido in both men and women.
- It is valued in traditional medicine for the many health benefits it provides, from graying hair to cancer.

RAW DRUGS

MUCUNA PRURIENS

ASPARAGUS RACEMOSUS

HYGROPHILA AURICULATA

CURCULIGO ORCIOIDES

ACACIA ARABICA

ACACIA ARABICA FLOWER

PHYSIOCHEMICAL ANALYSIS OF –THATHUVIUTHI KULIGAI

1. Loss on Drying:

An accurately weighed 2g of ***ThathuviuthiKuligai***formulation was taken in a tarred glass bottle. The crude drug was heated at 105^0C for 6 hours in an oven till a constant weight. Percentage moisture content of the sample was calculated with reference to the shade dried material.

2. Determination of total ash:

Weighed accurately 2g of ***ThathuviuthiKuligai***formulation was added in crucible at a temperature 600^0C in a muffle furnace till carbon free ash was obtained. It was calculated with reference to the air-dried drug.

3. Determination of acid insoluble ash:

Ash above obtained, was boiled for 5min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was burnt to a constant weight in a muffler furnace. The percentage of acid insoluble as was calculated with reference to the air-dried drug.

4. Determination of water soluble ash:

Total ash 1g was boiled for 5min with 25ml water and insoluble matter collected on an ash less filter paper was washed with hot water and ignited for 15 min at a temperature not exceeding 450^0C in a muffle furnace. The amount of soluble ash is determined by drying the filtrate.

5. Determination of water soluble Extractive:

5gm of air dried drug, coarsely powered ***Thathuviuthi Kuligai*** was macerated with 100ml of distilled water in a closed flask for twenty-four hours shaking frequently. Solution was filtered and 25 ml of filtrated was evaporated in a tarred flat bottom shallow dish, further dried at 100^0 C and weighted. The percentage of water soluble extractive was calculated with reference to the air-dried drugs.

6. Determination of alcohol soluble extractive:

2.5gm. of air dried drugs, coarsely powdered ***Thathuviuthi Kuligai*** was macerated with 50 ml. alcohol in closed flask for 24 hrs. With frequent shaking it was filtered rapidly taking precaution against loss of alcohol. 10ml of filtrate was then evaporated in a tarred flat bottom shallow dish, dried at 100^0C and weighted. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

S.No	Parameters	Percentage
1	Loss on drying	4.18%
2	Total ash value	4.93%
3	Acid insoluble ash	1.01%
4	Water soluble ash	1.04%
5	Water soluble extraction	36.29%
6	Alcohol soluble extraction	8.52%

The above stated physiochemical properties for the given sample certified to be present.

PRELIMINARY PHYTOCHEMICAL SCREENING

THATHUVIRUTHI KULIGAI

The preliminary phytochemical screening test was carried out for each extract of **Thathuviruthi Kuligai** as per the standard procedure.

1. Detection of alkaloids:

Extracts were dissolved individually in dilute Hydrochloric acid and filtered.

a) Mayer's Test: Filtrates were treated with Mayer's reagent (Potassium Mercuric Iodide). Formation of a yellow colored precipitate indicates the presence of alkaloids.

b) Wagner's Test: Filtrates were treated with Wagner's reagent (Iodine in Potassium Iodide). Formation of brown/reddish precipitate indicates the presence of alkaloids.

c) Dragendroff's Test: Filtrates were treated with Dragendroff's reagent (solution of Potassium Bismuth Iodide). Formation of red precipitate indicates the presence of alkaloids.

d) Hager's Test: Filtrates were treated with Hager's reagent (saturated picric acid solution). Presence of alkaloids confirmed by the formation of yellow colored precipitate.

2. Detection of carbohydrates:

Extracts were dissolved individually in 5 ml distilled water and filtered. The filtrates were used to test for the presence of carbohydrates.

a) Molisch's Test:

To 2 ml of plant sample extract, two drops of alcoholic solution of α- naphthol are added. The mixture is shaken well and few drops of concentrated sulphuric acid is added slowly along the sides of test tube. A violet ring indicates the presence of carbohydrates.

b) Benedict's Test:

Filtrates were treated with Benedict's reagent and heated gently. Orange red precipitate indicates the presence of reducing sugars.

3. Detection of glycosides:

Extracts were hydrolyzed with dil. HCl, and then subjected to test for glycosides.

a) Modified Borntrager's Test: Extracts were treated with Ferric Chloride solution and immersed in boiling water for about 5 minutes. The mixture was cooled and extracted with equal volumes of benzene. The benzene layer was separated and treated with ammonia solution. Formation of rose-pink color in the ammonical layer indicates the presence of anthranol glycosides.

b) Cardiac glycoside (Keller-Killiani test): Extract was shaken with distilled water (5 mL). To this, glacial acetic acid (2 mL) containing a few drops of ferric chloride was added, followed byH_2SO_4 (1 mL) along the side of the test tube. The formation of brown ring at the interface gives positive indication for cardiac glycoside and a violet ring may appear below the brown ring

4. Detection of saponins

a) Froth Test: Extracts were diluted with distilled water to 20ml and this was shaken in a graduated cylinder for 15 minutes. Formation of 1 cm layer of foam indicates the presence of saponins.

b) Foam Test: 0.5 gm of extract was shaken with 2 ml of water. If foam produced persists for ten minutes it indicates the presence of saponins.

5. Detection of phytosterols

a) Salkowski's Test: Extracts were treated with chloroform and filtered. The filtrates were treated with few drops of Conc. Sulphuric acid, shaken and allowed to stand. Appearance of golden yellow color indicates the presence of triterpenes.

6. Detection of phenols Ferric Chloride Test:

Extracts were treated with 3-4 drops of ferric chloride solution. Formation of bluish black color indicates the presence of phenols.

7. Detection of tannins Gelatin Test:

The extract is dissolved in 5 ml of distilled water and 2 ml of 1% solution of Gelatin containing 10% NaCl is added to it. White precipitate indicates the presence of phenolic compounds.

8. Detection of Flavonoids

a) Alkaline Reagent Test: Extracts were treated with few drops of sodium hydroxide solution. Formation of intense yellow color, which becomes colorless on addition of dilute acid, indicates the presence of flavonoids.

b) Lead acetate Test: Extracts were treated with few drops of lead acetate solution. Formation of yellow color precipitate indicates the presence of flavonoids.

9. Detection of proteins and aminoacids

a) Xanthoproteic Test: The extracts were treated with few drops of conc. Nitric acid. Formation of yellow color indicates the presence of proteins.

b) Ninhydrin Test: To the extract, 0.25% w/v ninhydrin reagent was added and boiled for few minutes. Formation of blue color indicates the presence of amino acid.

10.Detection of diterpenes

Copper Acetate Test:

Extracts were dissolved in water and treated with 3-4 drops of copper acetate solution. Formation of emerald green color indicates the presence of diterpenes

11. Gum and Mucilage:

To 1ml of extract add 2.5ml of absolute alcohol and stirring constantly. Then the precipitate was dried in air and examine for its swelling properties. Swelling was observed that will indicate presence of gum and mucilage.

12. Test for Fixed oils and Fats

a. Spot test :A small quantity of extract is pressed between two filter papers. Oil stain on the paper indicates the presence of fixed oils.

13. Test for Quinones

Extract was treated with sodium hydroxide blue or red precipitate indicates the presence of Quinones.

The Preliminary phytochemical studies of aqueous extract of **ThathuviruthiKuligai**were done using standard procedures. The results were presented in tables. The present study reveals that the bioactive compounds were present in all the extracts of **ThathuviruthiKuligai**.

S.No	Phytochemicals	Test Name	H2O Extract
1.	Alkaloids	Mayer's Test	**+ve**
		Wagner's Test	**+ve**
		Dragendroff's Test	**+ve**
		Hager's Test	**+ve**
2.	Carbohydrates	Molisch's Test:	**+ve**
		Benedict's Test	**+ve**
3.	Glycoside	Modified Borntrager's Test	**-ve**
		Keller Killiani	**-ve**
4.	Saponin	Froth Test	**+ve**
		Foam Test	**+ve**
5.	Phytosterol	Salkowski's Test	**-ve**
6.	Phenols	Ferric Chloride Test	**+ve**
7.	Tannins	Gelatin Test	**-ve**
8.	Flavonoids	Alkaline Reagent Test	**+ve**
		Lead acetate Test	**-ve**
9.	Proteins and amino acids	Xanthoproteic Test	**+ve**
10.	Diterpenes	Copper Acetate Test	**+ve**
11.	Gum & Mucilage	Extract + Alcohol	**+ve**
12.	Fat & Fixed Oil	Spot Test	**-ve**
13.	Quinones	NAOH + Extract	**+ve**

+ve/-ve present or absent if component tested

The above stated physiochemical properties for the given sample certified to be present.

BIO -CHEMICAL ANALYSIS OF THATHU VIRUTHI KULIKAI ANALYSED AT NATIONAL INSTITUTE OF SIDDHA

S. No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of sample	Dark brown in colour	
2.	**Solubility:** a. A little(500mg) of the sample is shaken well with distilled water. b. A little(500mg) of the sample is shaken well with con. HCl/Con. H_2So_4	Sparingly soluble	presence of silicate
3.	**Action of Heat:** A small amount(500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.	White fumes evolved	presence of Carbonate
4.	**Flame Test:** A small amount(500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared.	Absence of Copper
5.	**Ash Test: s** A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited	Appearance of Yellow colour flame	Absence of Sodium

Preparation of Extract: 5gm of**Thathuviruthikuligai** is weighed accurately and placed in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical elements in it.

S. No	EXPERIMENT	OBSERVATION	INFERENCE
	I.Test for Acid Radicals		
1.	**Test for Sulphate:** a.2ml of the above prepared extract is taken in a test tube to this added 2ml of 4% dil ammonium oxalate solution	No Cloudy appearance	Absence of **Sulphate**
2.	**Test for Chloride:** 2ml of the above prepared extracts is added with 2ml of dil-HCl is added until the effervescence ceases off.	cloudy appearance present	Presence of **Chloride**
3.	**Test for Phosphate:** 2ml of the extract is treated with 2ml of dil. ammonium molybdate solution and 2ml of con. HNo3	Yellow appearance was formed	Presence of **Phosphate**
4.	**Test for Carbonate:** 2ml of the extract is treated with 2mldil. magnesium sulphate solution	Cloudy appearance was evolved	Presence of **carbonate**
5.	**Test for Nitrate:** 1gm of the substance is heated with copper turning and concentrated H2So4 and viewed the test tube vertically down.	No Brown gas is evolved	Absence of Nitrate
6.	**Test for Sulphide:** 1gm of the substance is treated with 2ml of con. HCL	No Rotten Egg Smelling gas evolved	absent of Sulphide
7.	**Test for Fluoride & Oxalate:** 2ml of extract is added with 2ml of dil. Acetic acid and 2ml dil. calcium chloride solution and heated**.**	Presence Cloudy appearance	Presence of **fluoride and oxalate**
8.	**Test for Nitrite:** 3drops of the extract is placed on a filter paper, on that-2 drops of dil. acetic acid and 2 drops of dil. Benzidine solution is placed.	No Characteristic changes	Absence of Nitrite
9.	**Test for Borate:**2 Pinches(50mg) of the substance is made into paste by using dil. sulphuric acid and alcohol (95%) and introduced into the blue flame.	No appearance of Bluish green colour	Absence of borate

	II. Test for Basic Radicals		
1.	**Test for Lead:** 2ml of the extract is added with 2ml of dil. potassium iodine solution.	NoYellow Precipitate is obtained.	Absence of Lead
2.	**Test for Copper:** One pinch(50mg) of substance is made into paste with con. HClin a watch glass and introduced into the non-. luminuous part of the flame	No Blue colour apeared	Absence of copper
3.	**Test for Aluminium:** To the 2ml of extract dil. sodium hydroxide is added in 5 drops to excess.	No Yellow colour appeared	Absence of aluminium
4.	**Test for Iron:** a. To the 2ml of extract add 2ml of dil. ammonium solution b. To the 2ml of extract 2ml thiocyanate solution and 2ml of con HNo3 is added	No red colour appears	absence of Iron
5.	**Test for Zinc:** To 2ml of the extract dil. sodium hydroxide solution is added in 5 drops to excess and dil. ammonium chloride is added.	White precipitate is was formed	Presence of **Zinc**
6.	**Test for Calcium:** 2ml of the extract is added with 2ml of 4% dil. ammonium oxalate solution	Cloudy appearance and white precipitate was formed	Presence of **Calcium**
7.	**Test for Magnesium:** To 2ml of extract dil. sodium hydroxide solution is added in drops toexcess.	No White precipitate is obtained	Presence of **Magnesium**
8.	**Test for Ammonium:** To 2ml of extract 1 ml of Nessler's reagent and excess of dil. sodium hydroxide solution are added.	No Brown colour appeared	absence of ammonium
9.	**Test for Potassium:** A pinch(25mg) of substance is treated of with 2ml of dil. sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil. glacial acetic acid.	No Yellowish precipitate is obtained.	absence of Potassium
10.	**Test for Sodium**: 2 pinches(50mg) of the substance is made into paste by using HCl and introduced into the blue flame of Bunsen burner.	No yellow colour flame appeared	Absence of sodium

11.	**Test for Mercury**: 2ml of the extract is treated with 2ml of dil. sodium hydroxide solution.	No yellow precipitate is obtained	Absence of mercury
12.	**Test for Arsenic:** 2ml of the extract is treated with 2ml of dil. sodium hydroxide solution.	No brownish red precipitate is obtained	Absence of arsenic
	III. Miscellaneous		
1.	**Test for Starch:** 2ml of extract is treated with weak dil. iodine solution	blue colour developed	presence of starch
2.	**Test for Reducing Sugar:** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	Green colour developed	Prsence of **Reducing sugar**
3.	**Test for The Alkaloids**: a) 2ml of the extract is treated with 2ml of dil. potassium lodide solution. b) 2ml of the extract is treated with 2ml of dil. picric acid. c) 2ml of the extract is treated with 2ml of dil. phosphotungstic acid.	No Yellow colour developed	Presence of **Alkaloid**
4.	**Test for Tannic Acid:** 2ml of extract is treated with 2ml of dil. ferric chloride solution	No black precipitate is obtained	Absence of Tannic acid
5.	**Test for Unsaturated Compound:** To the 2ml of extract 2ml of dil. Potassium permanganate solution is added.	Potassium permanganate was not decolourised	Absence of unsaturated compound
6.	**Test for Amino Acid:** 2 drops of the extract is placed on a filter paper and dried well. 20ml of Biurette reagent is added**.**	violet colour developed	Presence of **Amino acids**
7.	**Test for Type of Compound:** 2ml of the extract is treated with 2 ml of dil. ferric chloride solution.	No green colour developed No red colour developedNo violet colour developed No blue colour developed	Absence ooxyquinolepine phrine and pyro catechol Antipyrine, Aliphatic amino acidsandmeconic acid are absent Apomorphine salicylate and Resorcinol areabsent.

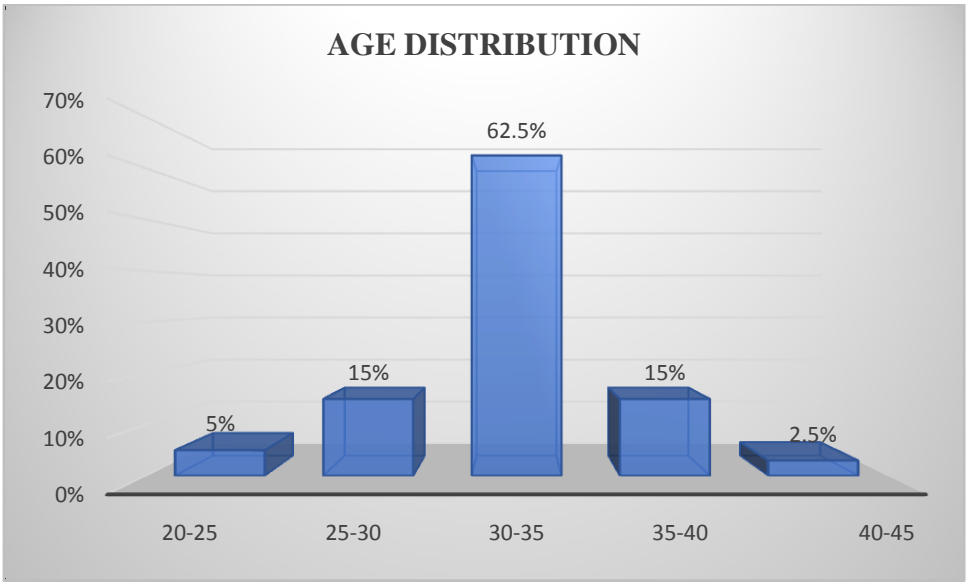
In biochemical analysis the trial drug contains very good antioxidant and aphrodisiac activity. So, the drug is proved that no adverse reaction was reported during the treatment period in all 40 cases. Therefore, I conclude that the trial drug is safe in male infertility cases.

OBSERVATION AND RESULTS

1. AGE DISTRIBUTION

Age (yrs)	Cases	
	No	**Percentage (%)**
20- 25	2	5
25-30	6	15
30-35	25	62.5
35-40	6	15
40-45	1	2.5

Fig. 1



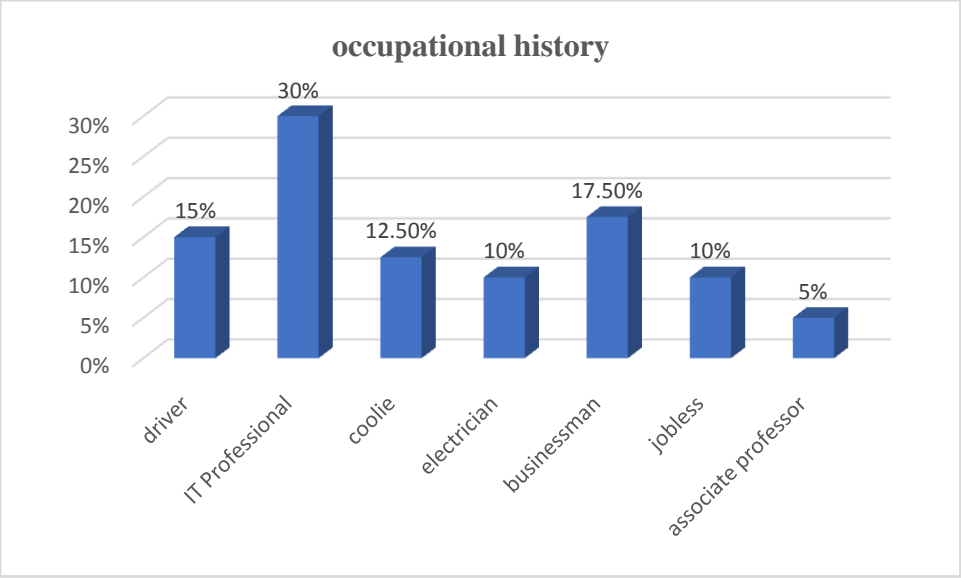
OBSERVATION:

Among 40 cases 2(5%) cases are between the age group of 20-25yrs,15% cases are between the age group of 25-20 yrs,62.5% cases are between the age group of 31-35 yrs,15% cases are between the age group of 36-40 yrs, **2.5%cases** are between the age group of 41 -45yrs

2) OCCUPATIONAL STATUS

Sl. No	Nature of Work	No. of Cases	Percentage
1	Driver	6	12.5%
2	IT professional	12	45%
3	Electrician	4	10%
4	Businessman	7	17.5%
5	Coolie	5	12.5%
6	Jobless	4	10%
7	Associate professor	2	5%
TOTAL		40	100%

Fig.2



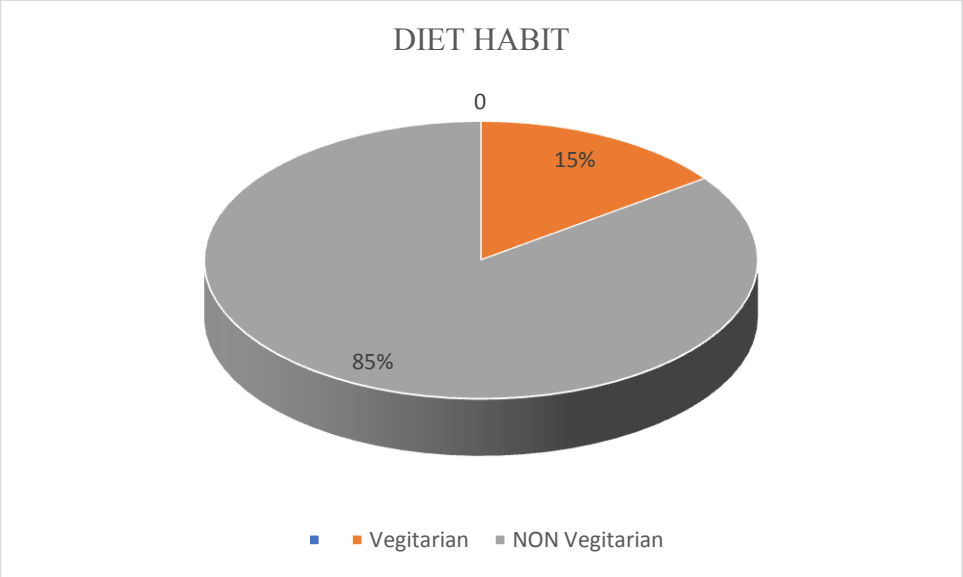
OBSERVATION:

Out of 40 patients 45% patients were working in hot atmosphere.IT Profession 12Patients (30%), businessman7patients [17.5] Drivers (15. 0%).working in hot atmosphere. This plays a vital role in male infertility. This may be one of the causes for infertility.

3. DIET HABITS:

S.NO	DIET HABITS	NUMBER OF THE CASES	PERCENTAGE
1	Vegetarian	6	15%
2	Non-vegetarian	34	85%
Total		**40**	**100%**

Fig.3



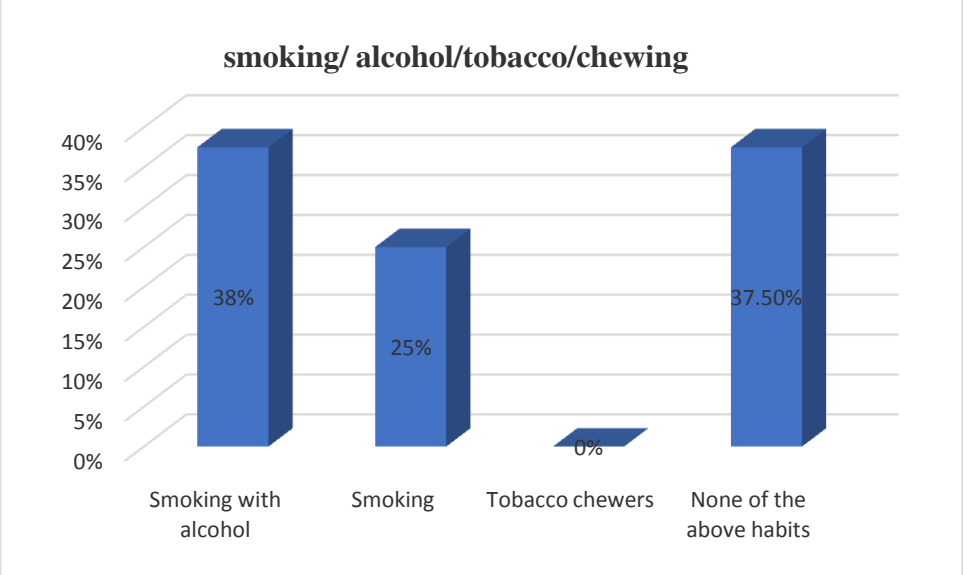
OBSERVATION:

Out of 40 patients 34(85%) were non-vegetarian and 6(15%) were vegetarian. This dietary style is more prone for developing infertility

4. PERSONAL *HABITS*

Personal habits (smoking/alcohol/tobacco chewing)	Case numbers	percentage
Smoking with alcohol	15	37.5%
Smoking	10	25%
Tobacco chewers	0	0%
None of the above habits	15	37.5%
Total	40	100%

Fig .4



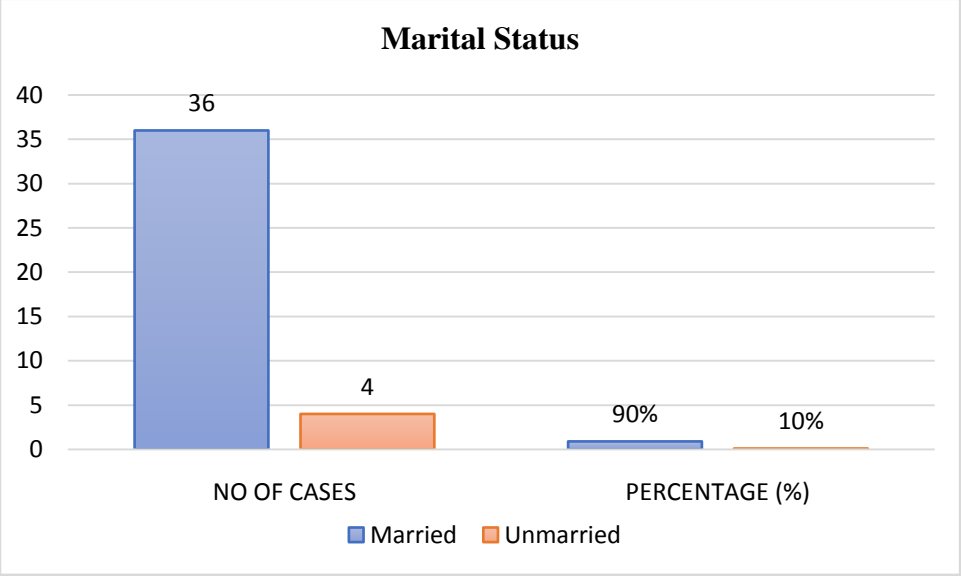
OBSERVATION:

Out of 40 patients 15[37.5%] patients were with None of the above habits,15[37.5%] patients were with smokers ans social drinkers,10[25%] patients were with only smokers.Smoking,alcohol and secondary life style is the major cause of male infertility because it increases the concentration of free radicals in the seminal fluid.

5.MARITAL STATUS

MARITAL STATUS	NO OF CASES	PERCENTAGE (%)
Married	36	90%
Unmarried	4	10%
Total	**40**	**100%**

Fig.5



OBSERVATION

Among 40 cases,

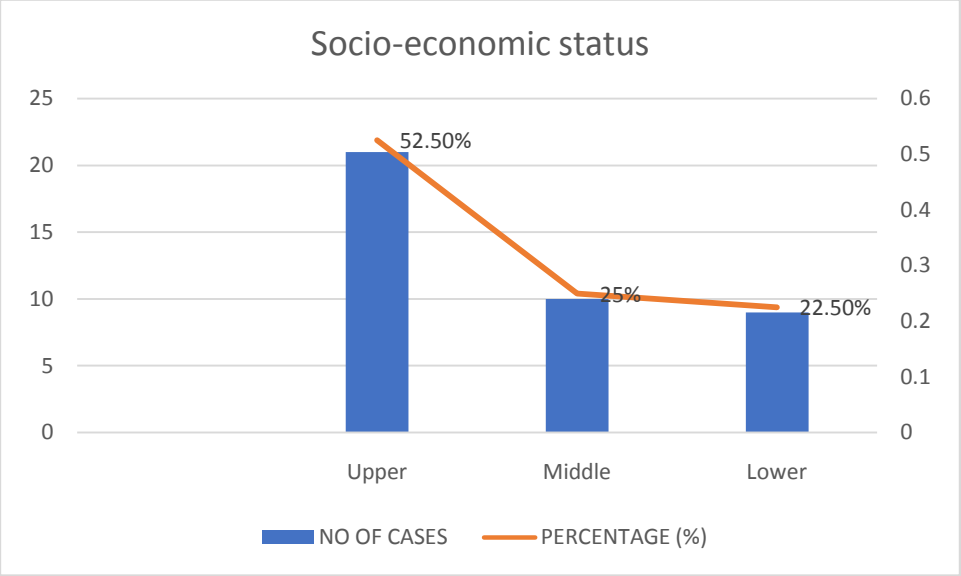
36(90%) cases were married 4 cases

(10%) were un married

6. SOCIO - ECONOMIC STATUS

SOCIO -ECONOMIC STATUS	NO OF CASES	PERCENTAGE (%)
Upper class	21	52.5%
Middle class	10	25%
Lower class	9	22.5%
Total	**40**	**100%**

Fig-6



OBSERVATION:

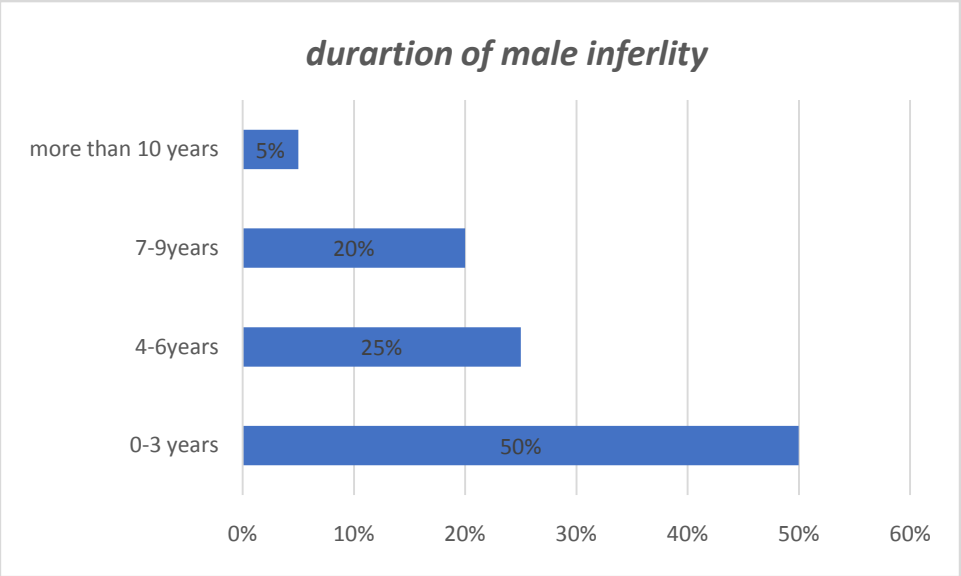
Out of 40 cases

- Upper class group - 21 cases (52.5%)
- Middle class group - 10 cases (25%)
- Lower class group - 9 caese (22.5%)

7. DURATION OF MALE INFERTILITY

Duration (years)	Cases	
	Numbers	Percentage (%)
0 – 3	20	50%
4 -6	10	25%
7- 9	8	20%
More than 10	2	5%
Total	40	100%

Fig-7:



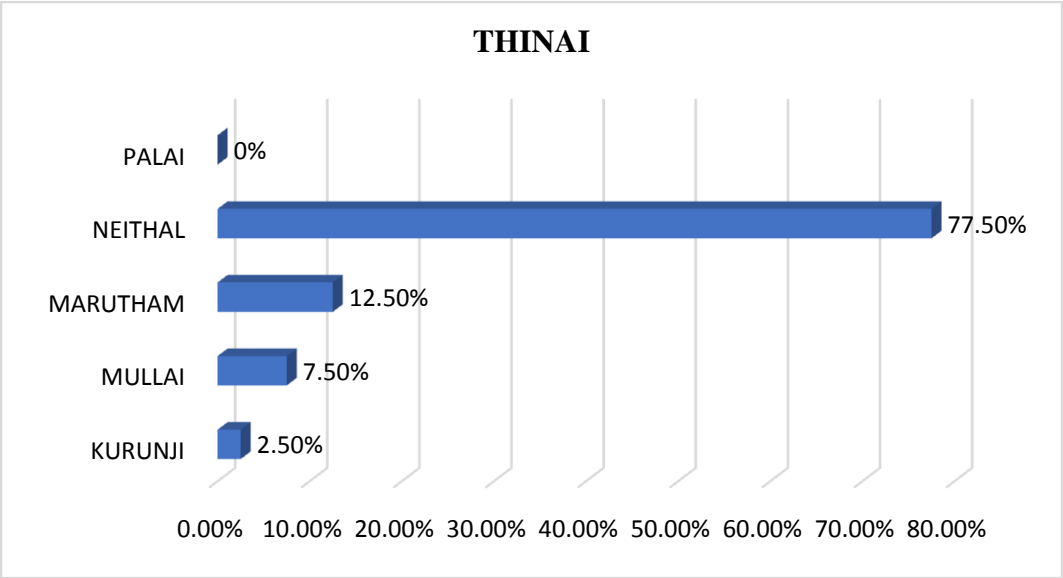
OBSERVATION:

- 50% of patients were within 0-3 years duration of infertility.
- 25% of patients were within 4years to 6 years of infertility.
- 20% of patients were within7yeara to 9years of infertility.
- 5% of patients were more than 10 years of infertility

8.THINAI

Thinai	cases	
	No	Percentage (%)
Kurunji	1	2.5%
Mullai	3	7.5%
Marutham	5	12.5%
Neithal	31	77.50%
Palai	0	0
Total	40	100

Fig-8



OBSERVATION

12.5 % of patients came from Marutham thinai

7.5% of patients from Mullai thinai.

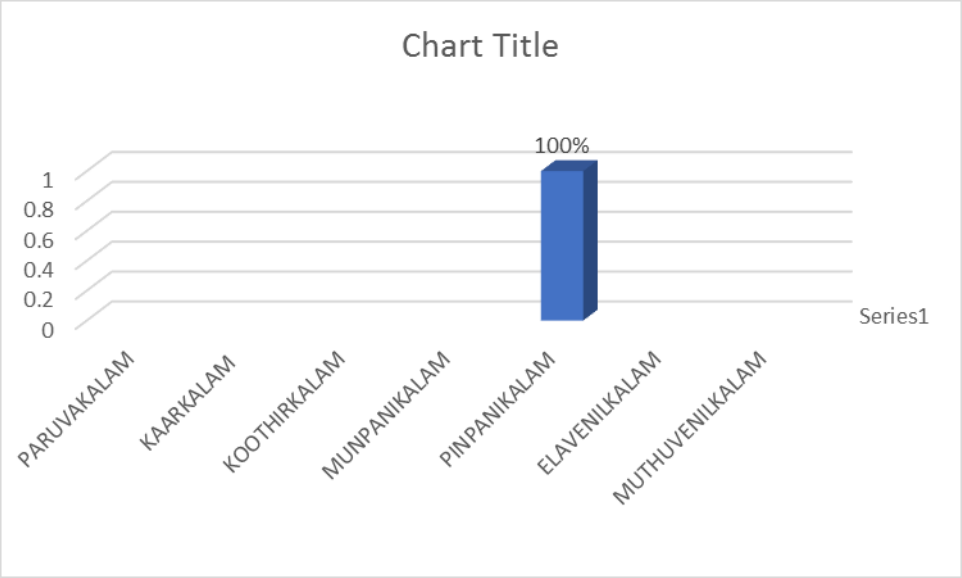
77.5% of patients from Neithal thinai

2.5% of patients from Kurunji thinai.

9. PARUVAKALAM

Paruvakalam	Cases	
	No	Percentage (%)
Karkalam	0	0
Koothirkalam	0	0
Munpanikalam	0	0
Pinpanikalam	40	100%%
Elavenilkalam	0	0
Muthuvenilkalam	0	0
Total	40	100

Fig-9:



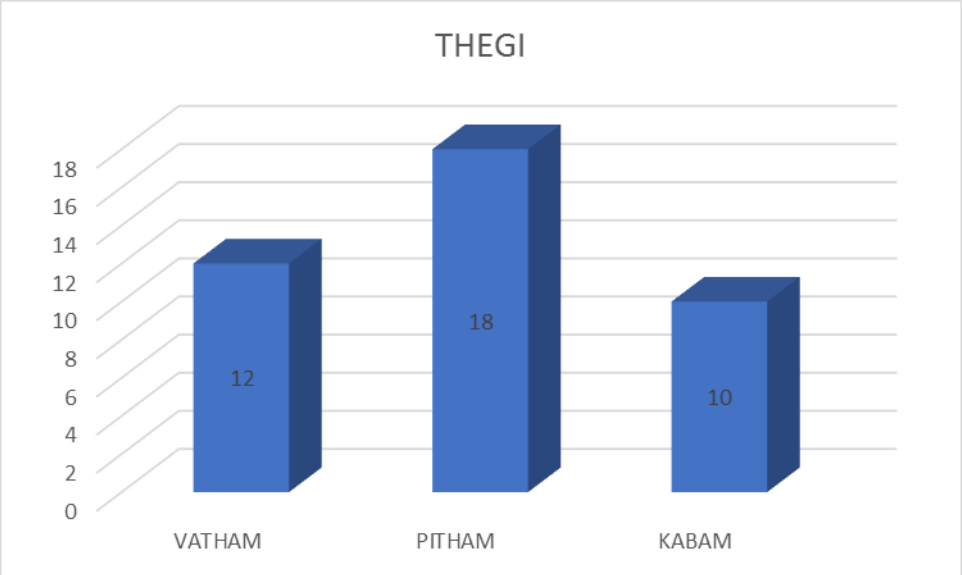
OBSERVATION:

100% of the patients came in pinpanikalam. The body which is already been weak due to the effect of previous season..

10. THEGI

Type of Theygi	No of cases	Percentage
Vatha thegi	12	30%
Pitha thegi	18	45%
Kaba thegi	10	25%
Total	40	100%

Fig – 10



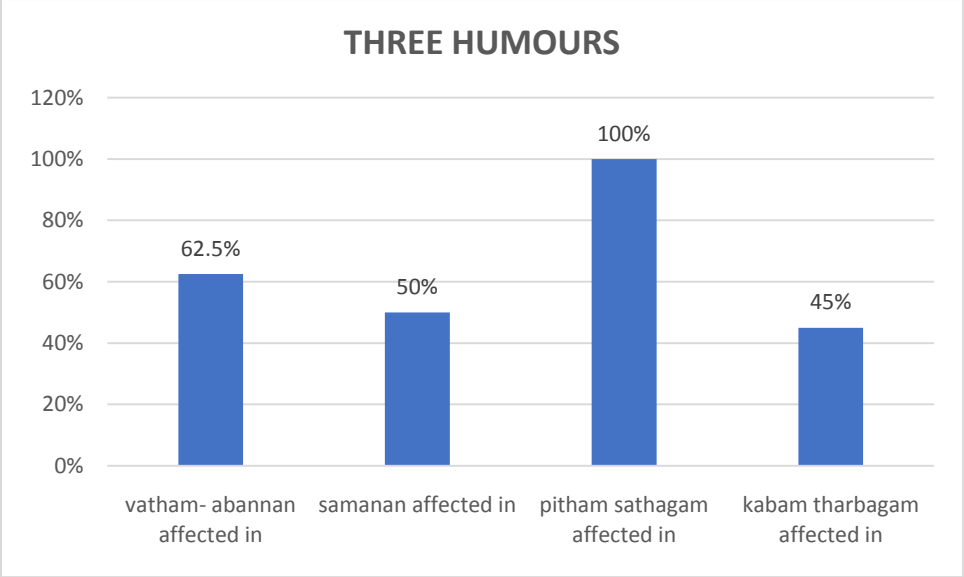
OBSERVATION:

- 30% of patients presenting with Vatha Thegi.
- 45% of patients presenting with Pitha Thegi.
- 25% of patients presenting with Kaba Thegi.
- *Pitha thegi* are *more prone to male infertility*

11.THREE HUMORS

Type of Humor	No of cases	Perceentage
Vatham Abannan affected in	24	60
Samanan affected in	20	50
Pitham Sathagam affected in	40	100
Kabam -Tharpagam affected in	26	65

Fig -11



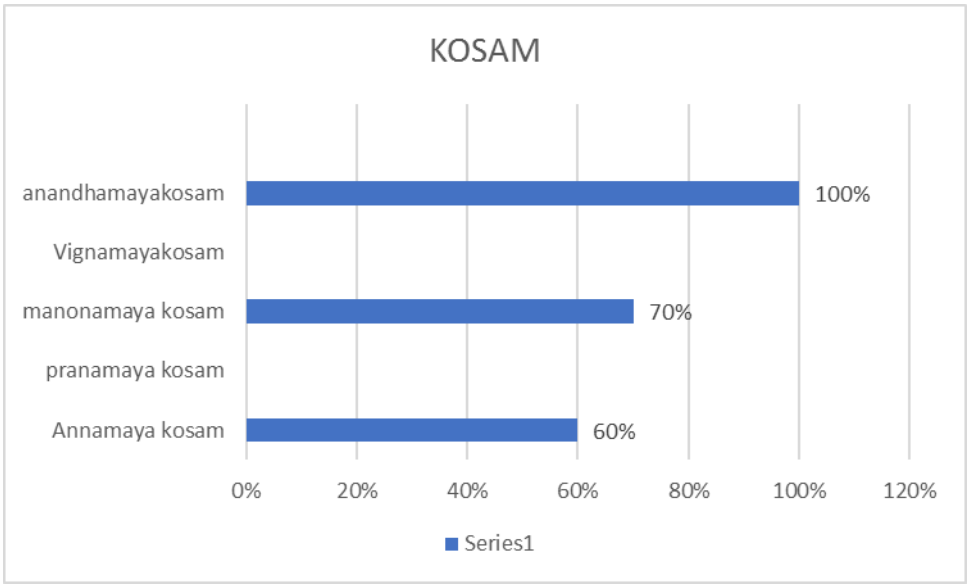
OBSERVATION:

- In Vatham 60% of patients (abannan) was affected due to pre-mature ejaculation, nocturnal ejaculation, burning micturition.
- In **Pitham 100%of patients** (Sathagam pitham) was affected due to *decreased sperm count, decreased sperm motility*.
- In Kabam 65% of patients (Tharpakam) was affected due to burning sensation of eyes.
- In Saamanan 20% of patients was affected.

12.KOSAM (Five sheaths)

Type of Kosam	No of cases	Percentage
Annamaya Kosam	24	60%
Pranamaya Kosam	0	0
Manomaya Kosam	28	70%
Vingnanamaya Kosam	0	0
Anandhamaya Kosam	40	100

Figt-12:



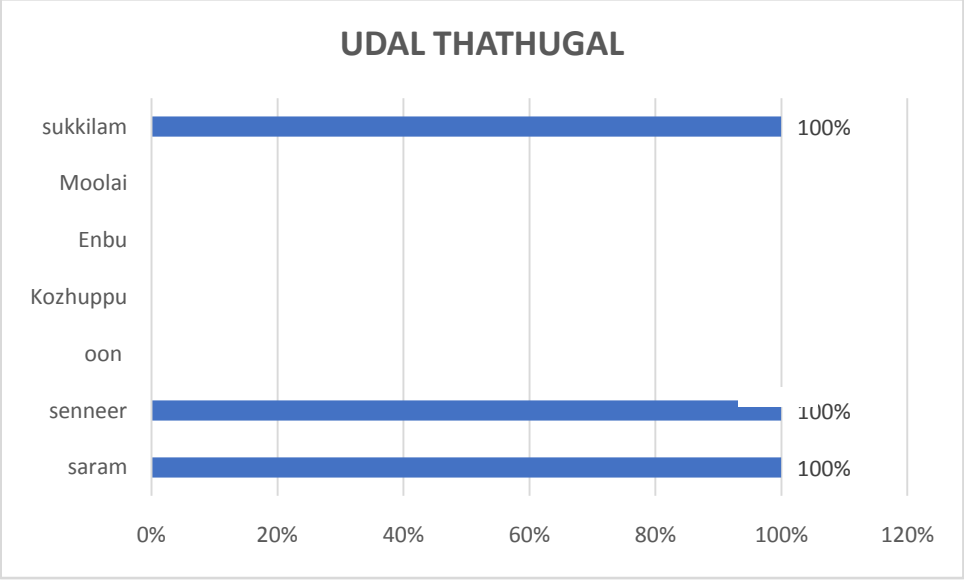
OBSERVATION:

- In 100%of the patients Annamayakosam was affected. (Two of the physical constituents saaram and senner affected).
- 70% of the patients ManomayaKosam was affected. (depression, Insomnia).
- 100%of the patients AnandhamayaKosam was affected. (decreased sperm count and motility).

13. UDAL THATHUGAL

Udal Thathugal	Cases	
	No	Percentage (%)
Saaram	40	100
Senneer	40	100
Oon	0	0
Kozhuppu	0	0
Enbu	0	0
Moolai	0	0
Sukkilam	40	100

Fig. 13



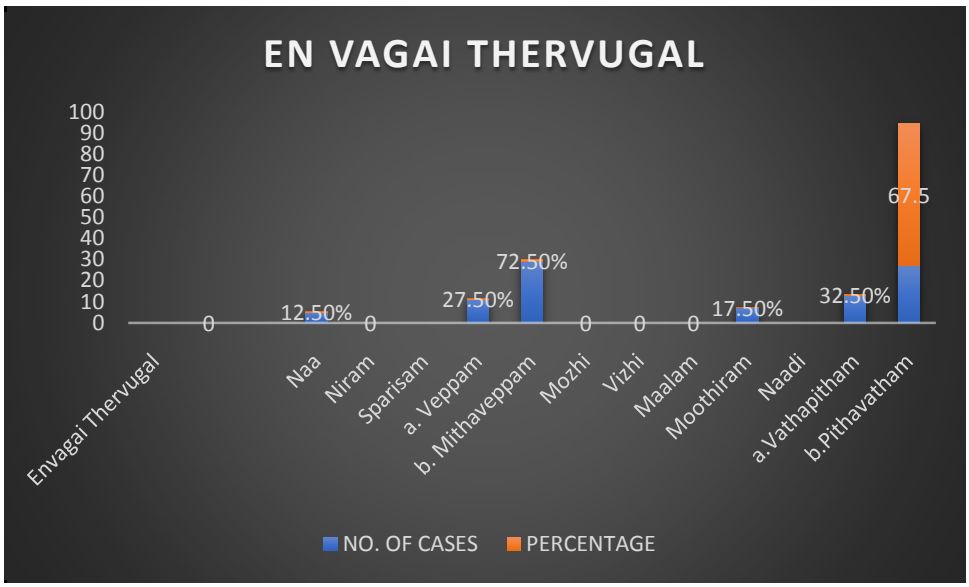
OBSERVATION:

- Saram was affected in 100% patients.
- Senneer was affected in 100% patients.
- Sukkilam was affected in 100% patients
    - Derangement of Saaram, Senneer, sukkilam or any one of this lead to development of infertility.

14.ENVAGAI THERVUGAL

Envagai Thervugal	Cases	
	No	Percentage (%)
Naa	5	12.5%
Niram	0	0
Sparisam a. Veppam b. Mithaveppam	 11 29	 27.5% 72.5%
Mozhi	0	0
Vizhi	0	0
Malam	0	0
Moothiram	7	17.5%
Naadi a. Vathapitham b. Pithavatham	 13 27	 32.5% 67.5%

Fig 14



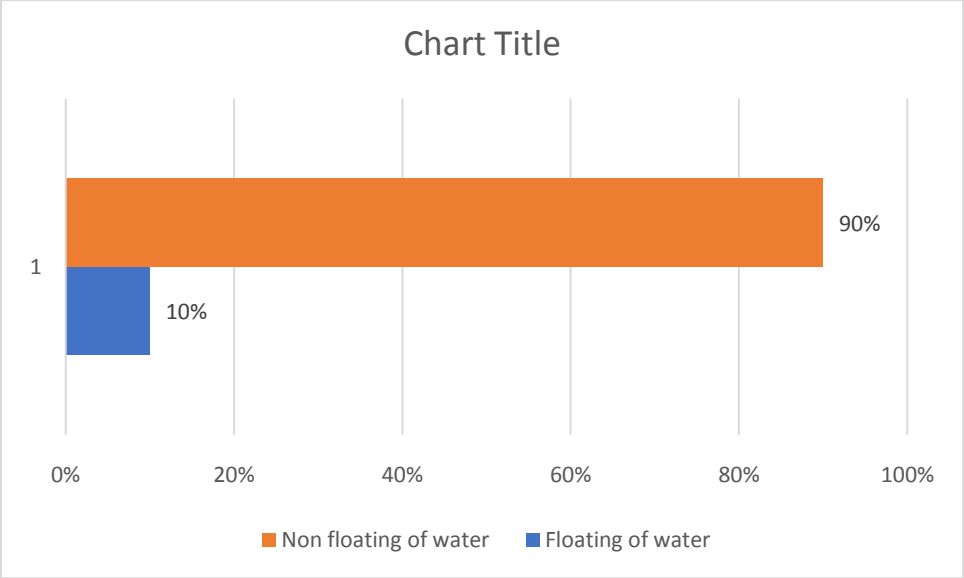
OBSERVATION:

- **Naa -**12.5% of patients presenting with Dryness of tongue.
- **Sparisam** – Sparisam was *Veppam in 27.5%patients* due to working in hot atmosphere.
  - Sparism was *Methavepam in 72.5%patients.*
- **Moothiram** was affected in 17.5% patients (burning micturition).
- **Naadi -**32.5% of the patients were presenting with Vatha Pitham Naadi.
  - 67.5% of the patients were presenting with Pitha Vatham Naadi.

15.BUONANCY OF WATER

Buoyancy on water	No cases	Percentage (%)
Floating on Water	4	10%
Not floating on Water	36	90%
Total	40	100

Fig. 15



OBSERVATION:

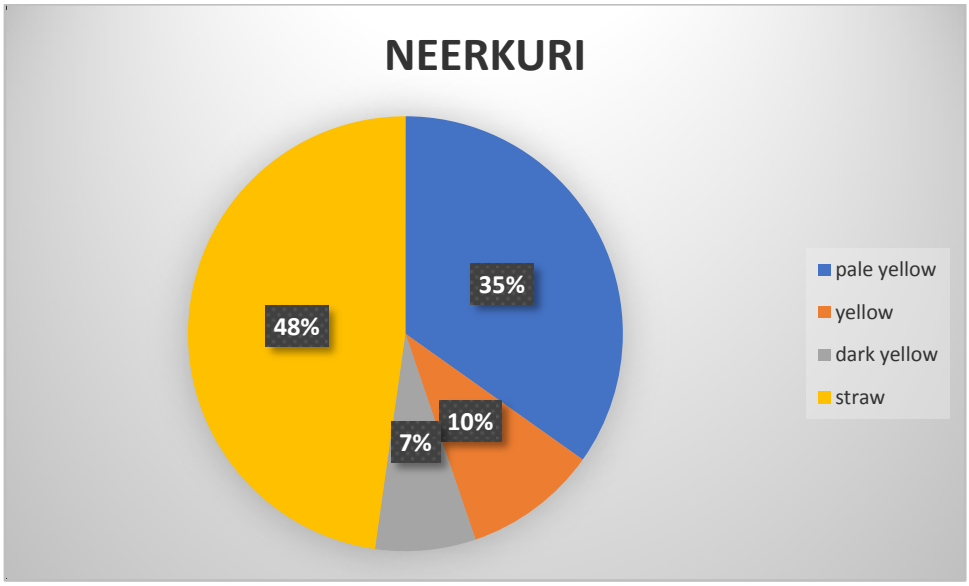
***Buoyancy on water*:**

- **The** important Siddha parameter to evaluate the Sperm.In 10% of the patient's sperm were floating on water indicating abnormal condition. 90% of the patients presented sperms not were floating on water indicating normal condition.

16.NEERKURI

Neerkuri	Cases	
	No	Percentage
Pale yellow	14	35%
Yellow	4	10
Dark yellow	3	7.5%
Straw	19	47.5%
Total	40	100

Fig-16:



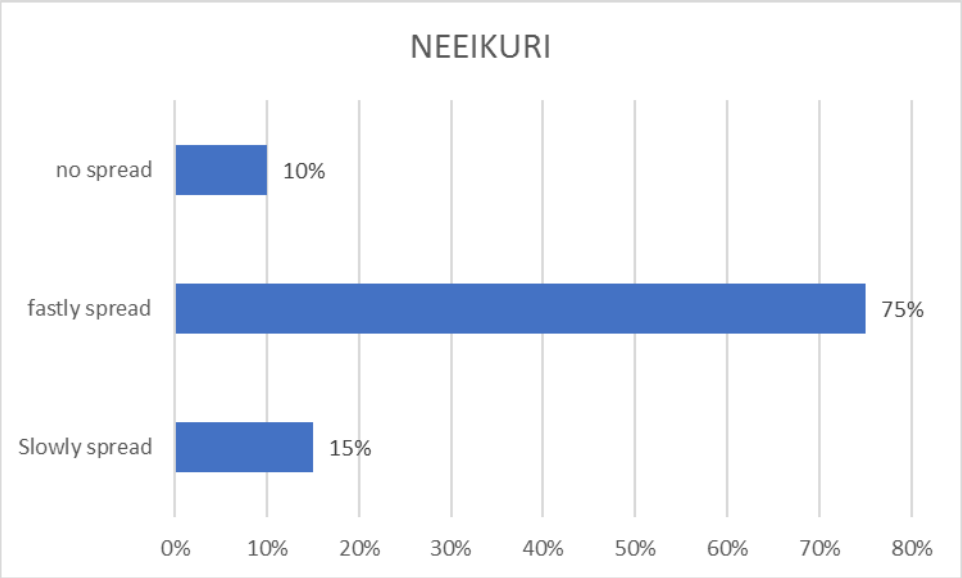
OBSERVATION:

- 35% of patients the colour of the urine was pale yellow colour.
- 10% of the patients the colour of the urine was yellow colour.
- 7.5% of the patients the colour of the urine was dark yellow in colour.
- 47.5% of the patients the colour of the urine was straw coloured urine

17. *NEIKURI*

Neeikuri	Cases	
	Numbers	Percentage
Slowly spread	6	15%
Fastly spread	30	75
No spread	4	10%
Total	40	100%

Fig. 17



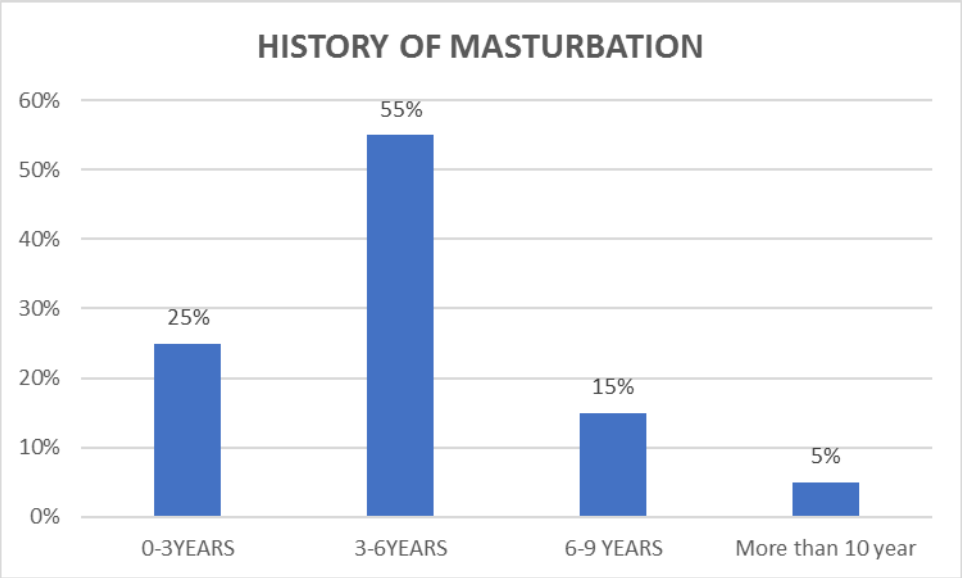
OBSERVATION:

- An important Siddha parameter reflecting the signs of Prognosis is spreading pattern of the in the urine.
- 15% of patients the Neikuri showed slowly spread pattern
- 75% of patients the Neikuri showed fastly spread pattern.
- 10%% of patients the Neikuri showed Stand still (Not spread)

18. HISTORY OF MASTURBATION

Duration (years)	Cases	
	No	Percentage (%)
0 – 3	10	25%
3-6	22	55%
6-9	6	15%
More than 10 years	2	5%
TOTAL	**40**	**100%**

Fig-18



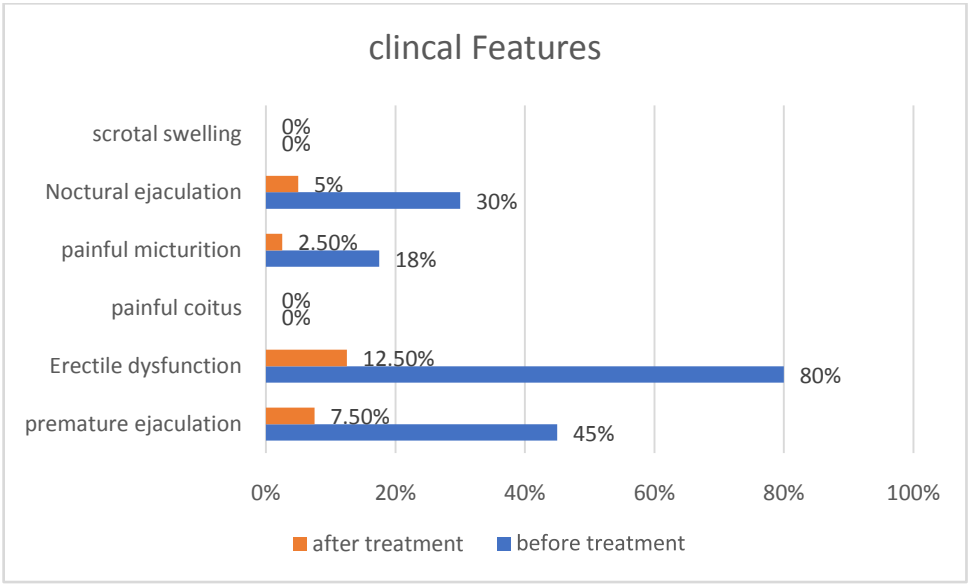
OBSERVATION:

- Masturbation habit was present in 40 patients Out of these 25% were within 0 to 3 years duration, 55% were within 3 years to 6 years duration
- 15% patient was within 6 to 10-year duration. Remaining 2.5% were more than 10 years duration. In all the 40 patients the frequency of masturbation was once in 3 days or weekly twice.

19. CLINICAL FEATURES

Symptoms	No of cases	Before treatment Percentage (%)	No. of cases	After treatment Percentage (%)
Premature ejaculation	18	45%	3	7.5%
Erectile dysfunction	33	80%	5	12.5%
Painful coitus	0	0	0	0
Painful Micturition	7	17.5%	1	2.5%
Nocturnal emission	10	30%	2	5%
Scrotal swelling	0	0	0	0

Fig-19:



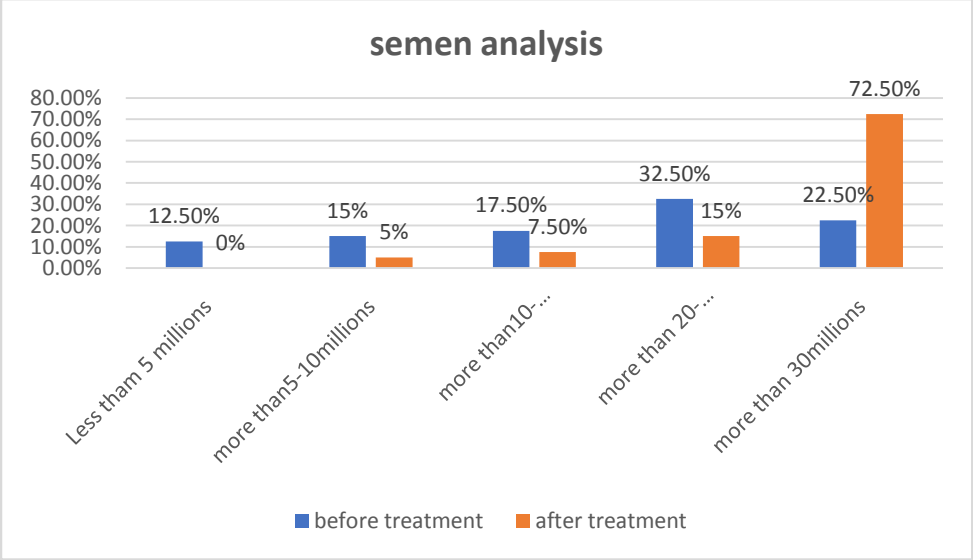
OBSERVATION:

- Premature ejaculation is the commonest symptom in infertility patients. 45% of patients suffered with this complaint. These patients were not fully satisfied during intercourse. *7.5% the patients were improved after the treatment*.
- 80% Patients came with erectile dysfunction, but not persistent. *12.5% the patient was improvement after treatment*. sometimes premature ejaculation and erectile dysfunction may be associated with painful coitus.
- 17.5%Patients came with painful micturition. *2.5%the patients were improvement after treatment.*
- Nocturnal emission is another important feature in infertility. Recurrent emission leads to decreased sperm count and motility. 30% patients came with this complaint, among them *5% were improved after the treatment.*

20. SEMEN ANALYSIS- SEMEN COUNT IMPROVEMENT PROFILE

Semen Count Before treatment presenting with	No of cases	%	Semen Count After treatment improved	No of cases	%
Less than 5 Million/ml	5	12.5%	Less than 5 Million/ml	0	0%
More than 5Million - 10Million/ml	6	15%	More than 5Million - 10Million/ml	2	5%
More than 11Million-20Million/ml	7	17.5%	More than 11Million-20Million/ml	3	7.5%
More than 21Million-30Million/ ml	13	32.5%	More than 21Million-30Million/ ml	6	15%
More than 30 Million/ml	9	22.5%	More than 30 Million/ml	29	72.5%

Fig-20:



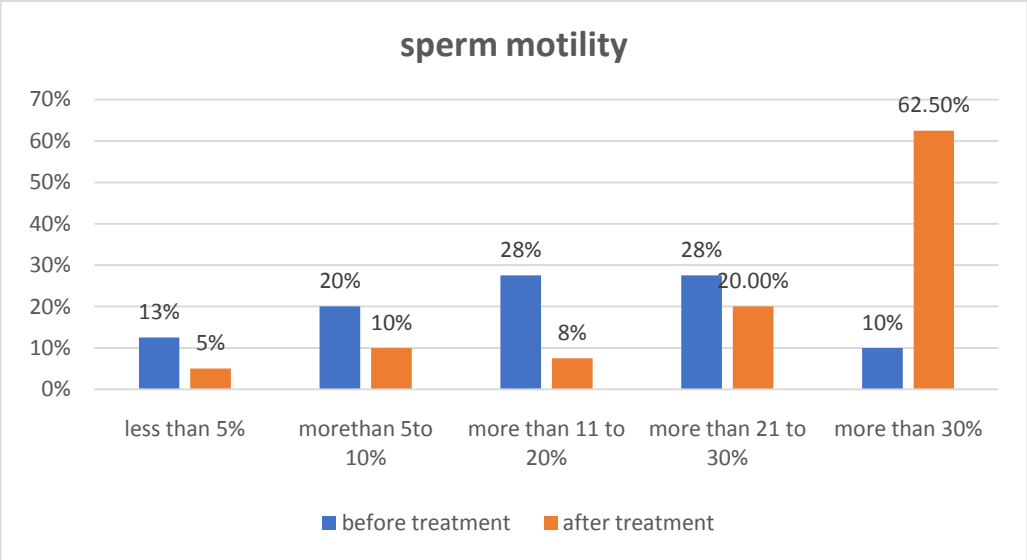
OBSERVATION:

- 5% of patients improved after treatment within 5 Million
- 5% of patients improved after treatment more than 5Million to 10Million.
- 7.5% of patients improved after treatment more than 11Million to 20Million.
- 22.5% of patients improved after treatment more than 21Million to 30Million
- 72.5%of patients improved after treatment more than 30 Million

21 SEMEN ANALYSIS - ACTIVE MOTILITY IMPROVEMENT PROFILE

Active Motility Before treatment presenting with	No of cases	%	Active Motility After treatment improved by	No of cases	%
Less than 5 %	6	12.5%	Less than 5 %	2	5%
More than 5% to 10%	8	20	More than 5% to 10%	4	10%
More than 11% to 20%	11	27.5%	More than 11% to 20%	3	7.5%
More than 21% to 30%	11	27.5	More than 21% to 30%	6	15%
More than 30 %	4	10%	More than 30 %	25	62.5%

Fig-21:



<u>OBSERVATION:</u>

- 5% of patients improved after treatment with Active Motility less than 5%
- 10% of patients improved after treatment with Active Motility more than 5% to 10%.
- 7.5% of patients improved after treatment with Active Motility more than 11% to 20%.
- 15% of patients improved after treatment with Active Motility more than 21% to30%.
- 62.5% of patients improved after treatment with Active Motility more than 30%.

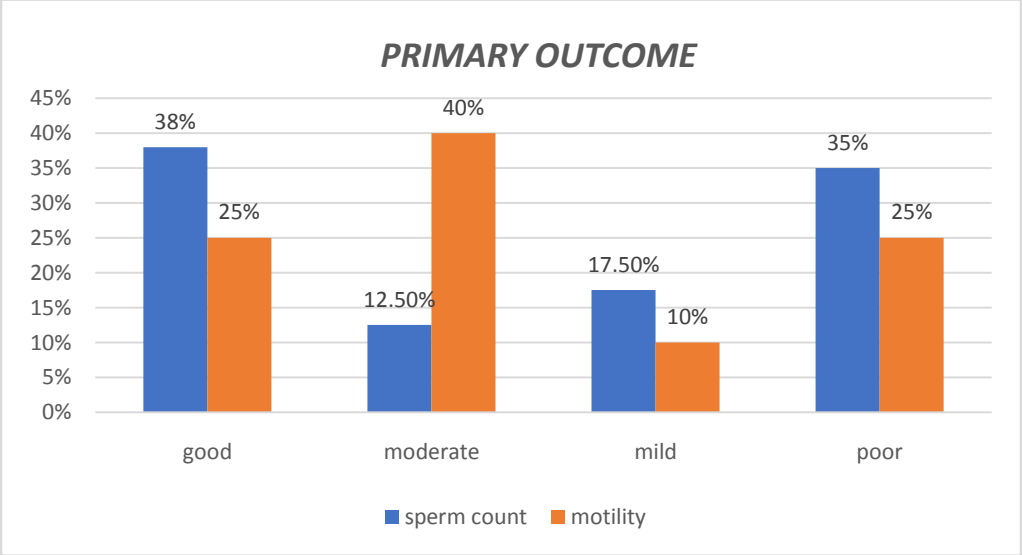
22. PRIMARY OUT COME

RESULT	SPERM COUNT *		No of cases	%	MOTILITY % #		No of cases	%
	FROM	TO			FROM	To		
GOOD	≤ 40 million / ejaculates	≥ 60 million / ejaculates	15	37.5	≤ 50%	≥ 70 %	10	25
MODERATE	≤ 40 million / ejaculates	> 50 million / ejaculates	4	12.5	≤ 50%	≥ 60 %	16	40
MILD	≤ 40 million / ejaculates	50 million / ejaculates	7	17.5	≤ 50%	> 50 %	4	10
POOR	1 million / ejaculates	≤ 40 million / ejaculates	14	35	≤ 50%	≤ 50%	10	25

Reference:

- As per 1999 WHO criteria (1) standard value for total number of spermatozoa ≥ 40 million per ejaculates.
- As per 1999 WHO criteria (1) standard value for motility is ≥ 50 % million per ejaculates.

Fig-22:



OBSERVATION: Primary out come regarding sperm count

- ❖ 37.5% of the patients falling into the category **GOOD**- increase of sperm count with range of 40-60Million/ml.
- ❖ 12.5% of the patients falling into the category **MODERATE**- increase of sperm count with range of 40 to more than 50Million/ml.
- ❖ 17.5% of the patients falling into the category **MILD**- increase of sperm count with range of 40-upto 50Million/ml.
- ❖ 35% of the patients falling into the category **POOR**- with the range of sperm count below 40Million/ml.

Primary out come regarding Active Motility

- ❖ 24% of the patients falling into the category **GOOD**- increase of Active Motility with range of 50%-70%.
- ❖ 41% of the patients falling into the category **MODERATE**- increase of Active Motility with range of 50 %to 60%.
- ❖ 10% of the patients falling into the category **MILD**- increase of Active Motility with range of with 50%.
- ❖ 25% of the patients falling into the category **POOR**- with range of Active Motility within 50%.

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. Bar diagram are used to describe the value of different variables for pictorial representation. The quantity variables were expressed as mean standard deviation and qualitative data as percentage. A probability value of <0.05 was considered to include as statistical significance. Paired t test was performed for determining the significance between and after treatment.

Results of statistical analysis of objective parameters (semen analysis) before and after treatment of 40 patients of Aan maladu.

Sno	Parameter	Mean		Probability value(p)	t value
		BT	AT		
1	Sperm count	21.01	60.6	0.0001	4.63
2	Sperm motility	23.25	36.75	0.0001	5.04

Results of statistical analysis of subjective parameters before and after treatment of 40 patients of Aan maladu.

The mean $\pm$ Standard deviation of sperm count before and after treatment were 21.01 and 60.6 respectively which is statistically significant (t=4.63 P<1.0000.

The mean $\pm$ Standard deviation of sperm motility before and after treatment were 23.25 and 36.75 respectively which is statistically significant (t=5.04 P<1.0000.

LAB INVESTIGATIONS

			Hb gm /dl		TRBC million /cu.mm	
SL.NO	OP NO	Study No	Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	1	13.5	14.2	4.4	4.1
2	K28219	2	15.5	15.8	4.7	5.4
3	J96266	3	13.5	14.0	4.6	5.5
4	I 60346	4	14.2	14.5	4.8	5.1
5	J73812	5	14.2	14.7	4.7	4.4
6	J60388	6	15.0	15.2	5.0	5.2
7	J97393	7	13.8	13.5	4.3	5.8
8	K26248	8	14.7	14.2	4.5	5.7
9	K27349	9	12.9	13.6	3.9	5.2
10	J94735	10	15.0	14.8	4.7	5.0
11	K26794	11	14.3	14.9	3.9	5.5
12	K04297	12	15.1	15.2	3.8	4.3
13	I 15340	13	16.0	15.7	4.7	5.4
14	I58885	14	15.8	16.3	5.9	5.4
15	K17053	15	16.0	15.9	5.8	5.8
16	J71138	16	14.5	14.7	4.3	4.7
17	K26420	17	14.7	14.9	5.5	5.3
18	K43307	18	15.2	15.3	4.8	5.0
19	J51711	19	12.0	12.6	5.1	5.3
20	K43136	20	16.0	15.8	4.9	5.7
21	K43014	21	15.8	15.9	5.1	5.1
22	K31241	22	13.5	13.8	4.3	5.4
23	I 46480	23	14.7	14.8	4.1	6.5
24	B95763	24	15.2	15.5	4.8	4.2
25	H84278	25	16.2	16.3	5.2	5.1
26	J95208	26	12.9	13.2	3.9	5.6
27	H24674	27	13.8	14.0	4.0	5.2
28	K34543	28	14.3	14.1	4.2	6.1
29	K39082	29	14.2	14.4	4.4	4.5
30	K35714	30	15.2	15.4	4.3	5.3
31	J28276	31	16.0	15.8	4.4	5.3
32	K14573	32	14.5	14.8	4.5	5.2
33	F046695	33	13.5	13.9	3.7	5.0
34	K27999	34	15.0	15.1	4.5	5.0
35	K40664	35	12.5	12.3	3.7	5.4
36	K15843	36	13.8	13.9	3.2	4.7
37	F032686	37	16.2	16.0	4.9	5.2
38	J16390	38	13.1	13.4	4.0	5.7
39	J65574	39	15.3	15.1	4.5	6.0
40	J99599	40	14.2	14.4	4.9	5.7

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BLOOD INVESTIGATIONS

SL.No	OP NO	TotalWBCcount (million/cu.mm)		DC %							
		Before Treatment	After Treatment	NEUTROPHILS%		LYMPHOCYTES		EOSINOPHILS%		MONOCYTES%	
				Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	9200	9000	66	60	27	31	-	-	07	09
2	K28219	5800	5600	54	53	42	43	-	-	04	04
3	J96266	8900	8700	56	55	37	38			07	07
4	I 60346	6300	6100	50	52	46	44			04	04
5	J73812	6200	5400	68	50	26	42			06	08
6	J60388	8200	6400	68	59	26	35			06	06
7	J97393	7900	8100	65	69	30	26			05	05
8	K26248	6700	6600	60	55	32	37			08	08
9	K27349	8200	8600	65	64	30	31			05	05
10	J94735	7400	6300	64	60	32	36			04	04
11	K26794	11400	10400	42	45	29	26	27	27	02	02
12	K04297	6900	6500	70	75	25	20			05	05
13	I 15340	7700	6700	66	64	30	32			04	04
14	I58885	5900	6000	51	50	43	44			06	06
15	K17053	10100	10100	50	55	25	25	22	19	03	01
16	J71138	10300	9400	59	57	32	34			09	09
17	K26420	5300	5300	66	60	29	33			05	07
18	K43307	6700	6800	40	42	47	45	11	11	02	02
19	J51711	6600	7700	63	63	32	31			05	06
20	K43136	9600	9900	69	68	27	28			04	04

BLOOD INVESTIGATIONS

SL.NO	OP NO	TotalWBCcount (million/cu.mm)		Differential Count							
				NEUTROPHILS %		LYMPHOCYTES%		EOSINOPHILS%		MONOCYTES%	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
21	K43014	7000	5100	70	65	22	30			08	05
22	K31241	7300	6300	52	53	39	38			09	09
23	I 46480	7900	8100	71	70	23	24			06	06
24	B95763	7200	7400	57	58	29	28			12	12
25	H84278	6100	6700	46	50	47	42			07	08
26	J95308	5500	6500	55	50	40	45			05	05
27	H24674	8200	7400	60	55	31	37			09	08
28	K34543	7900	6800	60	53	36	43			04	04
29	K39082	5800	5500	62	55	32	40			06	05
30	K35714	9000	8900	52	50	41	43			07	07
31	J28276	7300	7100	59	60	34	33			07	07
32	K14573	5600	5500	73	72	23	24			04	04
33	F046695	11600	7500	59	54	36	40			05	06
34	K27999	9400	8700	56	50	30	35		01	14	14
35	K40664	11800	11500	67	66	29	30			04	04
36	K15843	8700	8400	74	73	22	23			04	04
37	F032686	6900	6800	46	45	48	49			06	06
38	J16390	6900	7100	45	47	49	45			06	08
39	J65574	9900	8700	70	65	26	27			04	08
40	J99599	9100	9200	60	65	34	29			06	06

ERYTHROCYTE SEDEMENTATION RATE

SL.NO	OP NO	ESR		ESR	
		mm/1/2 Hr		mm/1 Hr	
		Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	8	9	12	13
2	K28219	6	7	12	11
3	J96266	4	6	12	15
4	I 60346	40	32	82	15
5	J73812	10	18	22	22
6	J60388	7	5	12	13
7	J97393	81	10	12	18
8	K26248	12	16	28	40
9	K27349	12	6	25	23
10	J94735	18	16	35	23
11	K26794	13	15	27	25
12	K04297	15	16	28	18
13	I 15340	12	7	23	19
14	I58885	15	Kna	Kna	18
15	K17053	17	14	15	12
16	J71138	25	22	48	46
17	K26420	kna	10	Kna	22
18	K43307	22	13	48	36
19	J51711	8	10	16	22
20	K43136	18	20	33	52
21	K43014	20	18	42	35
22	K31241	30	32	40	52
23	I 46480	10	12	18	22
24	B95763	20	18	32	34
25	H84278	30	28	38	35
26	J95308	6	8	18	20
27	H24674	18	19	21	23
28	K34543	25	22	38	35
29	K39082	Kna	Kna	Kna	Kna
30	K35714	18	20	40	44
31	J28276	13	15	27	28
32	K14573	10	12	28	34
33	F046695	5	8	18	25
34	K27999	6	12	18	25
35	K40664	18	20	35	40
36	K15843	19	25	37	45
37	F032686	20	18	44	38
38	J16390	15	12	32	28
39	J65574	40	33	55	48
40	J99599	20	17	20	17

LIPID PROFILE

SL.NO	OP NO	T. Cholesterol		HDL (mg/dl)		LDL (mg/dl)		VLDL (mg/dl)		TGL (mg/dl)	
		Before Treatment	After Treatment	Before Treatment	After	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatmen	After Treatment
1	J60382	118		32	35	95	98	68	75	138	127
2	K28219	163	152	48	46	112	108	52	55	210	119
3	J96266	219	212	42	45	129	121	44	48	221	212
4	I 60346	138	132	52	53	98	98	47	48	158	140
5	J73812	145	140	43	46	107	98	19	27	95	95
6	J60388	216	205	42	45	129	120	44	47	220	203
7	J97393	163	159	54	51	88	85	43	47	165	163
8	K26248	178	172	57	55	97	101	47	49	187	180
9	K27349	192	185	43	46	102	92	57	57	203	196
10	J94735	207	201	49	48	123	112	22	25	113	106
11	K26794	138	141	45	46	88	91	38	45	180	179
12	K04297	153	155	48	47	95	93	45	46	175	170
13	I 15340	116	117	52	53	108	106	53	52	128	131
14	I58885	152	148	39	42	89	94	32	36	160	159
15	K17053	162	158	42	38	76	79	48	47	188	184
16	J71138	152	148	48	45	98	95	52	55	168	162
17	K26420	172	165	45	43	123	112	138	125	188	180
18	K43307	118	122	55	53	92	96	68	72	158	152
19	J51711	152	147	47	45	90	93	55	58	165	170
20	K43136	128	133	43	46	87	83	68	72	162	166

SL.NO	OP NO	T. Cholesterol (mg/dl)		HDL (mg/dl)		LDL (mg/dl)		VLDL (mg/dl)		TGL (mg/dl)	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
21	K43014	161	164	43	39	97	101	19	24	97	123
22	K31241	200	195	50	40	122	120	23	25	117	110
23	I 46480	151	160	34	38	94	90	35	38	176	165
24	B95763	140	160	56	55	78	75	14	20	72	75
25	H84278	149	185	42	38	89	113	20	63	102	316
26	J95308	101	115	41	40	54	56	12	20	60	65
27	H24674	162	179	45	36	97	110	27	56	133	280
28	K34543	188	186	44	43	119	109	32	53	158	268
29	K39082	92	135	32	31	53	83	11	36	55	181
30	K35714	174	136	54	39	104	77	22	43	112	215
31	J28276	131	135	47	48	74	70	30	35	147	160
32	K14573	147	150	65	60	85	84	08	20	38	140
33	F046695	160	165	57	40	99	103	28	49	139	247
34	K27999	148	167	38	23	88	101	45	40	224	200
35	K40664	213	200	60	55	128	125	26	35	129	130
36	K15843	188	190	40	45	82	89	72	70	359	300
37	F032686	205	201	43	46	121	125	36	35	181	180
38	J16390	190	195	40	45	120	125	35	40	150	155
39	J65574	196	116	37	37	50	73	37	53	186	268
40	J99599	138	145	39	45	81	90	30	35	150	155

LIVER FUNCTION TEST **BLOOD SUGAR PROFILE**

SL. NO	OP NO	Serum Bilirubin (mg/dl)						Glucose Profile mg/dl					
		Direct		Indirect		Total		Fasting		Post prandial		Random	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	0.4	0.4	0.6	.3	1.0	0.7	78	89	112	128		
2	K28219	0.5	0.5	0.3	0.3	0.8	0.8	98	103	118	128		
3	J96266	0.2	0.4	0.4	0.3	0.5	0.7	106	98	116	128		
4	I 60346	0.3	0.5	0.4	0.3	0.6	0.8	95	92	125	133		
5	J73812	0.5	0.4	0.6	0.4	0.8	0.8	92	97	100	115		
6	J60388	0.3	0.6	0.2	0.5	0.9	1.1	103	88	111	128		
7	J97393	0.7	0.5	0.4	0.3	1.1	0.8	84	89	99	104		
8	K26248	0.3	0.5	0.4	0.4	0.7	0.9	89	101	118	115		
9	K27349	0.7	0.6	0.4	0.5	1.1	1.1	103	87	127	132		
10	J94735	0.2	0.5	0.5	0.4	0.7	0.9	99	104	151	143		
11	K26794	0.7	0.5	0.4	0.6	1.3	1.1	70	92	118	134		
12	K04297	0.4	0.3	0.1	0.5	0.6	0.8	95	98	138	138		
13	I 15340	0.5	0.4	0.6	0.5	1.1	0.9	102	100	135	139		
14	I58885	0.2	0.4	0.4	0.2	0.6	0.6	99	95	105	112		
15	K17053	0.3	0.3	0.5	0.6	0.8	0.9	87	94	87	135		
16	J71138	0.5	0.2	0.4	0.6	0.9	0.8	71	88	108	115		
17	K26420	0.2	0.5	0.4	0.3	0.6	0.8	102	103	131	142		
18	K43307	0.5	0.4	0.3	0.3	0.8	0.7	98	103	117	147		
19	J51711	0.3	0.3	0.6	0.5	0.9	0.8	98	105	138	122		

LIVER FUNCTION TEST

BLOOD SUGAR PROFILE

SL. N	OP NO	Serum Bilirubin (mg/dl)						Glucose Profile mg/dl					
		Direct		Indirect		Total		Fasting		Post prandial		Random	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
20	K43136	0.4	0.6	0.5	0.5	0.9	1.0	103	101	108	145		
21	K43014	0.6	0.4	0.5	0.5	1.1	0.9	88	93	126	138		
22	K31241	0.5	0.4	0.2	0.4	0.7	0.5	90	103	138	148		
23	I 46480	0.3	0.4	0.3	0.4	0.6	0.8	66	85	142	132		
24	B95763	0.4	0.3	0.6	0.5	1.0	0.8	108	87	110	118		
25	H84278	0.5	0.7	0.4	0.5	0.9	1.2	96	99	128	139		
26	J95308	0.7	0.4	0.5	0.6	1.2	1.0	90	74	113	122		
27	H24674	0.4	0.2	0.3	0.4	0.7	0.6	78	86	125	140		
28	K34543	0.2	0.2	0.3	0.3	0.5	0.5	108	95	142	135		
29	K39082	0.2	0.5	0.5	0.4	0.9	0.5	101	104	149	142		
30	K35714	0.8	0.4	0.6	0.6	1.2	1.0	95	98	138	125		
31	J28276	0.5	0.3	0.4	0.5	0.9	0.8	100	91	138	129		
32	K14573	0.3	0.4	0.2	0.3	0.5	0.7	105	82	129	132		
33	F046695	0.5	0.4	0.4	0.6	0.9	1.0	78	87	105	145		
34	K27999	0.4	0.5	0.7	0.5	1.1	1.0	89	84	129	150		
35	K40664	0.4	0.5	0.3	0.4	0.7	0.9	80	99	119	114		
36	K15843	0.4	0.3	0.2	0.5	0.6	0.8	100	105	125	121		
37	F032686	0.2	0.4	0.6	0.6	0.8	1.0	98	100	130	138		
38	J16390	0.3	0.4	0.4	0.3	0.7	0.6	108	78	110	124		
39	J65574	0.4	0.6	0.6	0.5	1.0	1.1	79	69	112	143		
40	J99599	0.2	0.5	0.5	0.3	0.7	0.8	114	68	138	140		

LIVER FUNCTION TEST

SL. NO	OP NO	SGOT (IU/L)		SGPT (IU/L)		serumAlkaline phosphatase (IU/L)		SerumAlbumin (gms/dl)		SerumGlobulin (gms/dl)		SerumTotal Protein (gms/dl)	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	23	21	38	40	66	70	4.1	4.1	3.2	2.7	7.1	7.3
2	K28219	25	23	32	29	68	71	4.3	4.1	2.6	2.8	7.5	7.5
3	J96266	18	20	28	27	63	60	4.1	4.2	2.8	2.7	6.8	6.9
4	I 60346	23	21	35	33	58	53	4.3	4.1	2.3	2.6	7.5	7.3
5	J73812	15	18	11	14	38	35	4.1	4.3	2.8	2.5	7.2	7.3
6	J60388	17	15	21	22	62	60	4.0	3.8	3.2	3.0	7.1	7.1
7	J97393	28	25	38	33	60	65	4.8	4.3	2.5	2.8	7.2	7.6
8	K26248	32	30	39	34	68	69	4.5	4.6	2.9	3.3	6.6	6.8
9	K27349	19	22	28	25	57	58	4.8	4.6	2.7	2.5	7.7	7.5
10	J94735	16	18	22	20	76	79	4.1	3.9	2.9	2.4	7.1	7.3
11	K26794	23	21	41	39	57	53	3.5	3.7	3.2	3.5	7.8	7.5
12	K04297	27	24	40	43	65	68	3.8	3.7	2.4	2.7	7.0	7.1
13	I 15340	31	30	28	27	79	77	4.3	4.1	3.5	3.3	6.5	6.7
14	I58885	19	18	31	34	97	95	4.0	3.7	2.4	2.6	6.4	6.2
15	K17053	22	20	37	34	87	90	3.9	3.8	2.5	2.9	6.6	6.7
16	J71138	28	31	78	81	85	88	3.9	3.6	2.7	3	7.2	7.4
17	K26420	41	37	95	90	95	92	4.0	3.8	2.9	3.2	7.5	7.3
18	K43307	33	36	68	71	82	85	3.8	4.0	3	3.3	7.3	7.5
19	J51711	46	43	81	77	90	93	3.6	3.8	3.5	3.7	7.4	7.7
20	K43136	58	55	68	71	78	75	4.1	4.1	3.9	4.1	7.3	7.5

LIVER FUNCTION TEST

SL. NO	OP NO	SGOT (IU/L)		SGPT (IU/L)		serumAlkaline phosphatase (IU/L)		SerumAlbumin (gms/dl)		SerumGlobulin (gms/dl)		SerumTotal Protein (gms/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	K43014	43	55	75	71	82	83	4.2	4.3	3.5	3.8	7.0	
22	K31241	70	46	110	115	69	70	3.5	3.7	3.1	3.3	6.8	7.0
23	I 46480	35	65	81	78	57	55	3.9	3.5	2.8	3	6.5	6.8
24	B95763	58	39	83	80	97	95	4.3	4.1	4.2	4.4	7.5	7.2
25	H84278	35	61	57	60	83	80	4.1	3.9	3.3	3.5	7.3	7.5
26	J95308	28	38	48	52	76	78	4.0	4.1	2.9	3.1	7.0	7.2
27	H24674	15	25	35	39	75	74	3.3	3.5	2.5	2.9	6.3	6.5
28	K34543	48	18	59	55	88	86	3.8	3.5	4.4	4.6	7.9	7.6
29	K39082	15	44	40	50	80	85	3.2	3.1	4.2	4.3	7.1	7.3
30	K35714	28	25	11	18	65	84	4.3	4.1	4.0	3.7	7.5	7.2
31	J28276	22	20	27	23	72	69	4.0	3.8	2.5	2.8	6.8	6.9
32	K14573	18	21	32	29	79	75	3.5	3.7	2.8	2.6	6.8	7.0
33	F046695	30	24	23	27	63	68	3.8	3.6	2.6	2.9	6.6	6.8
34	K27999	26	21	18	21	68	71	4.2	4.0	3.7	3.8	6.7	6.6
35	K40664	17	18	23	26	75	72	4.0	3.8	2.3	2.5	7.2	7.1
36	K15843	23	20	29	25	71	68	3.7	3.6	2.8	2.6	6.8	6.5
37	F032686	17	19	25	23	63	61	3.8	3.9	3.4	3.7	7.5	7.1
38	J16390	29	25	16	19	62	65	3.7	3.4	3.7	3.4	6.8	6.4
39	J65574	21	23	19	15	71	72	3.3	3.4	3.1	3.2	7.5	7.7
40	J99599	14	17	15	18	74		3.5	3.6	2.8	2.9	6.8	6.9

URINE INVESTIGATION

SL.NO	OP NO	URINE							
						After Treatment			
		SL.N	Sugar	Deposits		Albumin	Sugar	Deposits	
					Epi Cells			Pus Cells	Epi Cells
1	J60382	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	02-4 cells	03-4 cells
2	K28219	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	02-4 cells	02-4 cells
3	J96266	NIL	NIL	03-4 cells	03-3 cells	NIL	NIL	02-4 cells	02-4 cells
4	I 60346	NIL	NIL	02-4 cells	02-3 cells	NIL	NIL	03-3 cells	02-4 cells
5	J73812	NIL	NIL	02-4 cells	02-3cells	NIL	NIL	02-4cells	03-3 cells
6	J60388	NIL	NIL	02-4 cells	03-4 cells	NIL	NIL	02-3cells	02-4 cells
7	J97393	NIL	NIL	03-3 cells	02-4 cells	NIL	NIL	02-3cells	02-4 cells
8	K26248	NIL	NIL	02-3 cells	02-4 cells	NIL	NIL	03-4 cells	02-4 cells
9	K27349	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	02-4 cells	03-3 cells
10	J94735	NIL	NIL	03-4 cells	03-3 cells	NIL	NIL	02-4 cells	02-4 cells
11	K26794	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	0-2cells	02-4 cells
12	K04297	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	03-3 cells	02-4 cells
13	I 15340	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-3 cells	03-3 cells
14	I58885	NIL	NIL	03-3 cells	03-3 cells	NIL	NIL	02-3cells	02-4cells
15	K17053	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-4 cells	02-3cells
16	J71138	NIL	NIL	01-2 cells	02-4 cells	NIL	NIL	02-4 cells	02-3cells
17	K26420	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-4 cells	03-4 cells
18	K43307	NIL	NIL	03-3 cells	03-3 cells	NIL	NIL	01-3 cells	02-4 cells
19	J51711	NIL	NIL	02-4 cells	02-4cells	NIL	NIL	02-4cells	02-4 cells
20	K43136	NIL	NIL	02-4 cells	03-3 cells	NIL	NIL	01-2cells	02-4 cells
21	K43014	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-3cells	03-3 cells
22	K31241	NIL	NIL	03-3 cells	02-4 cells	NIL	NIL	01-3 cells	02-3 cells
23	I 46480	NIL	NIL	02-4cells	02-4 cells	NIL	NIL	02-4 cells	02-3cells

URINE INVESTIGATION

Sl. No	OP NO	URINE							
						After Treatment			
		SL.	umin Sugar	Deposits		Albumin	Sugar	Deposits	
				SL.N	Epi Cells			02-3 cells	Epi Cells
24	B95763	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	02-3cells	02-4 cells
25	H84278	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	02-4 cells	03-3 cells
26	J95308	NIL	NIL	03-4 cells	03-3 cells	NIL	NIL	02-4 cells	02-4 cells
27	H24674	NIL	NIL	02-4 cells	02-3 cells	NIL	NIL	02-4 cells	02-4 cells
28	K34543	NIL	NIL	02-4 cells	02-3cells	NIL	NIL	03-3 cells	01-3 cells
29	K39082	NIL	NIL	02-4 cells	03-4 cells	NIL	NIL	02-4cells	03-3 cells
30	K35714	NIL	NIL	03-3 cells	02-4 cells	NIL	NIL	02-3cells	02-4 cells
31	J 28276	NIL	NIL	02-3 cells	02-4 cells	NIL	NIL	02-3cells	02-4 cells
32	K14573	NIL	NIL	02-3cells	02-4 cells	NIL	NIL	03-4 cells	02-4 cells
33	F046695	NIL	NIL	03-4 cells	03-3 cells	NIL	NIL	02-4 cells	03-3 cells
34	K27999	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-4 cells	02-4cells
35	K40664	NIL	NIL	02-4 cells	01-3cells	NIL	NIL	02-4 cells	02-3cells
36	K15843	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	03-3 cells	02-3cells
37	F032686	NIL	NIL	03-3 cells	03-3 cells	NIL	NIL	02-3 cells	01-3cells
38	J16390	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-3cells	02-3cells
39	J65574	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-3 cells	01-3 cells
40	J99599	NIL	NIL	02-4 cells	02-4 cells	NIL	NIL	02-3cells	04-5 cells

RENAL FUNCTION TEST

NO	OP NO	UREA mg/dl		CREATININE mg/dl		U RIC ACID mg/dl	
SL. NO	OP NO	BT	AT	BT	AT	BT	AT
1	J60382	15	14	1.1	0.9	7.3	7.1
2	K28219	16	18	0.8	1.1	7.5	7.2
3	J96266	18	18	1.4	0.9	7.8	7.6
4	I 60346	20	22	1.0	0.8	7.2	7.5
5	J73812	25	23	1.0	1.2	6.9	7.0
6	J60388	12	18	1.1	0.9	7.0	6.7
7	J97393	23	20	1.1	1.0	7.1	7.4
8	K26248	18	17	0.7	1.1	7.3	7.1
9	K27349	15	18	1.2	1.0	6.8	6.6
10	J94735	25	23	1.2	0.8	5.7	5.9
11	K26794	35	37	0.6	0.9	7.2	7.0
12	K04297	27	25	0.8	1.0	5.7	5.8
13	I 15340	15	20	1.0	0.8	7.2	7.0
14	I58885	18	18	1.0	1.0	5.0	5.2
15	K17053	23	21	1.1	1.0	6.7	6.3
16	J71138	12	18	1.1	1.0	6.5	6.3
17	K26420	19	21	1.2	1.1	6.7	6.9
18	K43307	24	19	0.9	0.8	6.5	6.7
19	J51711	27	24	0.9	0.9	6.5	6.3
20	K43136	18	21	1.1	1.2	7.2	7.0
21	K43014	21	18	0.9	1.0	5.8	5.9
22	K31241	18	16	0.8	0.5	6.3	6.1
23	I 46480	27	25	1.0	0.9	7.5	7.3
24	B95763	26	28	0.6	0.8	6.8	7.2
25	H84278	30	28	0.9	1.0	6.1	6.0
26	J95308	12	14	0.6	0.8	5.9	6.1
27	H24674	17	15	1.1	1.0	7.0	7.2
28	K34543	17	15	1.3	1.1	7.2	7.3
29	K39082	19	16	1.1	0.9	3.5	3.7
30	K35714	21	23	0.9	0.8	5.6	5.4
31	J28276	15	18	0.8	0.9	6.4	6.8
32	K14573	15	18	0.5	0.9	7.0	7.4
33	F046695	12	18	0.8	1.0	6.9	6.6
34	K27999	18	21	0.6	0.5	5.0	5.2
35	K40664	12	18	1.0	0.8	7.4	7.2
36	K15843	17	21	0.4	0.7	6.3	6.5
37	F032686	23	27	1.2	1.0	7.2	7.1
38	J16390	21	24	0.9	0.7	6.6	7.0
39	J65574	19	17	1.0	0.9	5.9	6.3
40	J99599	20	17	1.1	0.9	7.4	7.7

SEMEN ANALYSIS

Sl. No	OP NO	Volume ml		Liquefaction Time (minute)		Fructose	
		Sl.	AT	BT	AT	BT	AT
1	J60382	1.5	2.5	20	20	PRESENT	PRESENT
2	K28219	1.0	2.0	30	30	PRESENT	PRESENT
3	J96266	2.0	3.5	30	30	PRESENT	PRESENT
4	I 60346	2.0	3.0	20	30	PRESENT	PRESENT
5	J73812	1.5	2.5	40	35	PRESENT	PRESENT
6	J60388	1.5	1.0	30	30	PRESENT	PRESENT
7	J97393	2.5	5.1	30	25	PRESENT	PRESENT
8	K26248	1.5	2.0	20	30	PRESENT	PRESENT
9	K27349	2.5	4	30	30	PRESENT	PRESENT
10	J94735	4.0	5.9	30	30	PRESENT	PRESENT
11	K26794	2.0	2.5	20	30	PRESENT	PRESENT
12	K04297	1.4	2.6	30	30	PRESENT	PRESENT
13	I 15340	2.5	3.0	10	15	PRESENT	PRESENT
14	I58885	1.2	2.6	30	35	PRESENT	PRESENT
15	K17053	5.5	7.5	20	25	PRESENT	PRESENT
16	J71138	3.5	3	30	30	PRESENT	PRESENT
17	K26420	3.0	4.5	30	25	PRESENT	PRESENT
18	K43307	1.6	2.5	40	30	PRESENT	PRESENT
19	J51711	3.0	4.0	30	30	PRESENT	PRESENT
20	K43136	2.0	3.0	25	25	PRESENT	PRESENT
21	K43014	6	6.5	30	20	PRESENT	PRESENT
22	K31241	3.5	5	30	30	PRESENT	PRESENT
23	I 46480	2	2.5	30	30	PRESENT	PRESENT
24	B95763	2.5	6.5	20	8	PRESENT	PRESENT
25	H84278	4	1.5	30	30	PRESENT	PRESENT
26	J95308	1.5	2.8	30	28	PRESENT	PRESENT
27	H24674	2	2.5	15	25	PRESENT	PRESENT
28	K34543	1.5	2	30	35	PRESENT	PRESENT
29	K39082	2	3	30	20	PRESENT	PRESENT
30	K35714	2	2.6	20	30	PRESENT	PRESENT
31	J 28276	1.5	2.5	20	30	PRESENT	PRESENT
32	K14573	2.5	3.2	20	30	PRESENT	PRESENT
33	F046695	1.5	1	30	30	PRESENT	PRESENT
34	K27999	1.5	4	10	20	PRESENT	PRESENT
35	K40664	1.5	2.5	30	30	PRESENT	PRESENT
36	K15843	3	2.5	30	30	PRESENT	PRESENT
37	F032686	2.5	3	30	30	PRESENT	PRESENT
38	J16390	3	4.5	30	30	PRESENT	PRESENT
39	J65574	2	3	15	20	PRESENT	PRESENT
40	J99599	2	3.5	20	30	PRESENT	PRESENT

SEMEN ANALYSIS

		Sperm Count/ml		Motility %		Morphology%	
SL.	OP NO	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
1	J60382	12	48	30	70	40	90
2	K28219	33.5	50	20	50	3.8	37
3	J96266	16	38	10	30	1	15
4	I 60346	28	80	10	10	40	50
5	J73812	40	86	40	45	40	50
6	J60388	30	35	10	10	90	90
7	J97393	10	27.5	20	22	94	95
8	K26248	29	60	10	10	50	78
9	K27349	38	70	05	10	57	70
10	J94735	12	19.2	30	40	40	56
11	K26794	8	19	40	50	40	55
12	K04297	2.32	8	10	15	40	58
13	I 15340	3	32	40	55	38	50
14	I58885	39	80	40	50	3	27
15	K17053	11.5	45	30	40	42	50
16	J71138	28	60	10	10	50	50
17	K26420	40	110	20	80	40	90
18	K43307	20	45	40	55	8	38
19	J51711	3	28	05	10	70	90
20	K43136	23.5	40	30	30	90	90
21	K43014	24.8	58	30	70	40	90
22	K31241	39.4	90	10	15	73	90
23	I 46480	32	45	10	20	50	50
24	B95763	28	76	30	35	40	60
25	H84278	11	70	30	60	60	60
26	J95308	24	38	10	10	4.2	38.5
27	H24674	7.92	25	10	10	20	30
28	K34543	8.0	62.8	20	53	30	76
29	K39082	10	43	10	60	30	50
30	K35714	125	225	40	50	9.4	35
31	J 28276	6	14	10	10	40	40
32	K14573	12.5	24	20	30	25	40
33	F046695	28	58	30	10	30	40
34	K27999	3.1	9.8	30	10	40	40
35	K40664	6	45	40	55	10	60
36	K15843	38.2	108	30	60	75	80
37	F032686	3.8	27	40	55	55	60
38	J16390	22	56	30	60	40	60
39	J65574	38	98	20	50	40	70
40	J99599	8	26	30	55	48	70

DISCUSSION

In developing country likeIndia, one in every four couples found to be affected by infertility. In 2010 almost 50 million couple's world wide unable to have a child after five years of marriage. Infertility rate has hardly changed over the past 20 years. The global health community has made great success in improving the infertility care in the past decade. Infertility can lead to distress and depression as well as discrimination and ostracism. infertility can be caused by poor sexual life style habits that are easily remedied. Heavy usage of alcohol, tobacco drugs, tight underwares or pants which raise the scrotal temperature and reduce the sperm count. Infections play a vital role in male infertility that block the ducts through which the sperm travels. Exposure to metals such as lead, chemical and pesticide plays a major role in male infertility. Auto immunity in which antibodies or cells of the human immune system attack sperm cells mistaking them as toxic invaders. Nowa day's male infertilitytreatmeant is a challenging task. In recent years siddha system of medicine have bloomed up in treating male infertility with high success rate.

There was a time when infertility was only limited to women but in present scenario male infertility is blamed in 59% of cases where couples could not conceive naturally. Most of the cases hail from IT back ground. The change in life style even among small income group has led to increase in infertility rate and lack of physical activities. Any infections that occur at an early age in a male child and low economic standards can also lead to rise in male infertility.

The most common problems men face is low sperm count, low motility rate and morphological abnormalities. The reproductive age for men is 18 to 50

Age Distribution:

Among 40 cases

- 5% cases are between the age group of 20-25yrs
- 15% cases are between the age group of 25-20yrs
- 62.5% cases are between the age group of 31-35yrs
- 15% cases are between the age group of 36-40yrs
- **2.5%cases** are between the age group of 41 -45yrs

Inference:

- In my study the prevalence of the disease was found to be more in the age growth ranging from 31years to 35years (62.5%)

Occupational history:

- Out of 40 patients 45% patients were working in hot atmosphere.IT Profession 12Patients (30%), businessman7patients [17.5] Drivers (15. 0%).working in hot atmosphere.
- This plays a vital role in male infertility. This may be one of the causes for infertility.

Food habits

- Out of 40 patients 36(90%) were non-vegetarian and 4(10%) were vegetarian.
- This dietary style is more prone for developing infertility

Personal habits

- Out of 40 patients 15[37.5%] patients were with none of the above habits
- 15[37.5%] patients were with smokers ans social drinkers.
- 10[25%] patients were with only smokers.

Marital status

- Among 40 cases 36cases (90%) were married remaining 4 cases were unmarried

Socio economic status

Out of 40 cases

- Upper class group -21 cases (52.5%)
- Middle class group -10 cases (25%)
- Lower class group -9 caese (22.5%)

Inference:

- In this study most of the patients coming from upper class group 21 cases (52.5%)

Duration of Male Infertility

- **50% of patients were within 0-3 years duration of infertility**.
- 25% of patients were within 4years to 6 years of infertility.
- 20% of patients were within7yeara to 9years of infertility.
- 5% of patients were more than 10 years of infertility.,

Inference:

- In this study most of the cases 20 (50%) were within 0-3 years duration of infertility

Thinai:

- 12.5% of patients came from Maruthamthinai.
- 7.5%of patients from Mullaithinai.
- **77.5%of patients fromNeithalthinai.**
- 2.5% of patients from kurunjithinai.

Inference

- In this study most of the cases 31(77.5%) patients coming from neithalthinai..

Paruvakaalam:

- 100% of the patients came in pinpanikalam.
- The body which is already been weak due to the effect of previous season.

Thegi:

- 30% of patients presenting with VathaThegi.
- 45% of patients presenting with PithaThegi.
- 25% of patients presenting with KabaThegi.
    - ***Pithathegi*** are ***more prone to male infertility*.**

Three Humors:

- In Vatham 60% of patients (abannan) was affected due to pre-mature ejaculation, nocturnal ejaculation, burning micturition.
- In **Pitham 100%of patients** (Sathagampitham) was affected due to *decreased sperm count, decreased sperm motility.*
- InKabam65% of patients (Tharpakam) was affected due to burning sensation of eyes.
- In Saamanan 20% of patients was affected.

Kosam (Five sheaths)

- In 100%of the patientsAnnamayakosam was affected. (Two of the physical constituents saaram and senner affected).
- 70% of the patients ManomayaKosam was affected. (depression, Insomnia).
- *100%of the patients AnandhamayaKosam was affected*. (**decreased sperm count and motility**).

UdalThathukkal

- Saram was affected in 100% patients.
- Senneer was affected in 100% patients.
- Sukkilam was affected in 100% patients
- Derangement of Saaram, Senneer, sukkilam or any one of this lead to development of infertility.

Envagaitheryu

Naa:

- 12.5% of patients presenting with Dryness of tongue.

Sparisam:

- Sparisam was *Veppam in 27.5%patients* due to working in hot atmosphere.
- Sparism was ***Methavepam in 72.5%patients***.

Moothiram:

- moothiram was affected in 17.5% patients (burning micturition).

Naadi:

- -32.5% of the patients were presenting withVathaPithamNaadi.
- *67.5% of the patients* were presenting with**PithaVathamNaadi**.

Sukkilam:

***Buoyancy on water*: The** important Siddha parameter to evaluate the Sperm.In 10% of the patient's sperm were floating on water indicating abnormal condition. 90% of the patients presented sperms not were floating on water indicating normal condition.

Neerkuri

The important Siddha diagnostic parameter.

- 35% of patients the colour of the urine was pale yellow colour.
- 10% of the patients the colour of the urine wasyellow colour.
- 7.5% of the patients the colour of the urine was dark yellow in colour.
- 47.5% of the patients the colour of the urine was straw coloured urine.

Neikuri

An important Siddha parameter reflecting the signs of Prognosis is spreading pattern of the in the urine.

- 15% of patients the Neikuri showed slowly spread pattern.
- 75% of patients the Neikuri showedfastly spread pattern.
- 10%% of patients the Neikuri showed Stand still (Not spread)

History of Masturbation

- Masturbation habit was present in 40 patients Out of these 25% were within 0 to 3 years duration.
- 55% were within3 years to 6 years duration.
- 15% patient was within 6 to 10-year duration.
- Remaining 2.5% were more than 10 years duration.
- In all the 40 patients the frequency of masturbation was once in 3 days or weekly twice.

Clinical Features

- Premature ejaculation is the commonest symptom in infertility patients. 45% of patients suffered with this complaint. These patients were not fully satisfied during intercourse. *7.5% the patients were improved after the treatment*.
- 80% Patients came with erectile dysfunction, but not persistent. *12.5% thepatient was improvement after treatment*. sometimes premature ejaculation and erectile dysfunction may be associated with painful coitus.
- 17.5%Patients came with painful micturition. *2.5%the patients wereimprovement after treatment.*
- Nocturnal emission is another important feature in infertility. Recurrent emission leads to decreased sperm count and motility. 30% patients came with this complaint, among them *5% were improved after the treatment.*

Semen analysis- Semen Count After treatment improvement profile

- 5% of patients improved after treatment within 5 Million / ml
- 5% of patients improved after treatment more than 5Million to 10Million.
- 7.5% of patients improved after treatment more than 11Million to 20Million.
- 22.5% of patients improved after treatment more than 21Million to 30Million
- 72.5%of patients improved after treatment more than 30 Million

Semen analysis -Active Motility After treatment improvement profile

- 5% of patients improved after treatment with Active Motility less than 5%
- 10% of patients improved after treatment with Active Motility more than 5% to 10%.
- 7.5%of patients improved after treatment with Active Motility more than 11% to 20%.
- 15% of patients improved after treatment with Active Motility more than 21% to30%.
- 62.5%of patients improved after treatment with Active Motility more than 30%.

PRIMARY OUTCOME OF THE TREATMENT WITH THE TRAIL DRUG THATHU VIRUTHI KULIGAI

Primary out come regarding sperm count

- 37.5% of the patients falling into the category **GOOD**- increase of sperm count with range of 40-60Million/ml.
- 12.5% of the patients falling into the category **MODERATE**- increase of sperm count with range of 40 to more than 50Million/ml.
- 17.5% of the patients falling into the category **MILD**- increase of sperm count with range of 40-upto 50Million/ml.
- 35% of the patients falling into the category **POOR**- with the range of sperm count below 40Million/ml.

Primary out come regarding Active Motility

- 24% of the patients falling into the category **GOOD**- increase of Active Motility with range of 50%-70%.
- 41% of the patients falling into the category **MODERATE**- increase of Active Motility with range of 50 %to 60%.
- 10% of the patients falling into the category **MILD**- increase of Active Motility with range of with 50%.
- 25% of the patients falling into the category **POOR**- with range of Active Motility within 50%.
- In clinical study, out of 40 patients 37 patients (92.5%) were showed improvement in clinical lab investigation (semen analysis). The sperm count and sperm motility were improved in those patients. All the 37 patients (92.5%) were relived from clinical symptoms.
- The sperm count and sperm motility differences before and after treatment showed statistically significant in Male infertility patients.
- The mean $\pm$ Standard deviation of sperm count before and after treatment were 21.01 and 60.6 respectively which is statistically significant ($t=4.63$ $P<1.0000$.
- The mean $\pm$ Standard deviation of sperm motility before and after treatment were 23.25 and 36.75 respectively which is statistically significant ($t=5.04$ $P<1.0000$.

SUMMARY

The main aim of this study is to document the effectiveness of siddha medicine thathuviruthikulikai (Internal medicine) in the management of AANMALADU (Male infertility).

The objective of this study is the Clinical studies conducted in 40 cases. The raw drug was purchased from reputed country medical shop in Chennai and drug authentication by Assisstant Professor of Medicinal Botany.

The drug was prepared as per standard operating procedure mentioned in the siddha literature in Gunapadam laboratory of National Institute of Siddha.

The standardization of study drug was carried out in the Biochemistry lab of NIS.It revealed the presence of **chloride, fluoride, carbonate** with the study drug

The clinical study was conducted with a well-defined protocol and a proper proforma after getting the approval of the Institutional Ethical Committee. **(IEC NO.2016/11-04/14.10.2016]**

The study data were registered in CTRI (Clinical Triall Registry of India) with **ID NO: CTRI/2018/01/011580**

After screening 60 cases study based on the inclusion criteria and exclusion criteria reporting at the OPD of Maruthuvam, 40 cases were selected for induction to the study. Before enrolment into the trial the informed consent was obtained from the patients.

The aim of the study is to increase the sperm count and sperm motility in male infertility patients. The duration of administration of study drug 48 days. The study drug dose was illanthaikottaialavu [325mg] twice a daily with cow milk

Before Starting the treatment semen analysis, routine blood and urine examination were taken in all 40 patients. Siddha methods like three Humor, Thegi, Kosangal, udalthathukkal, Envagaithervu, neeikuri, nerkuri and buoyancy of Semen on water were analysed in all 40 Cases.

Patients were instructed to come for clinical assessment once in 15 days. They were also instructed to bring back the unconsumed drug during the next visit and return the same. In every visit the clinical assessment was made.

At the end of the treatment reduction of clinical symptoms and improvement in clinical lab para meters (Sperm count and motility) in all the 40 patients. 72.5% of patients improved after treatment more than 30 Million in sperm count.24% of the patients were presenting increase of Active Motility with range of 50%-70%. 41% of the patients were presenting increase of Active Motility with range of 50 %to 60%.10% of the patients were presenting increase of Active Motility with range of with 50%. 25% of the patients were presenting with range of Active Motility with less than 50%.

The cost of medicine is comparatively low. The ingredients were easily available and the rural people will be benefited more.

The mean $\pm$ Standard deviation of sperm count before and after treatment were 21.01 and 60.6 respectively which is statistically significant ($t=4.63$ $P<1.0000$.

The mean $\pm$ Standard deviation of sperm motility before and after treatment were 23.25 and 36.75 respectively which is statistically significant ($t=5.04$ $P<1.0000$.

I have concluded the siddha medicine thathuviruthikulikai was effective in treatment of “Aanmaladu” (Male infertility especially oligospermia and asthenozoospermia).

CONCLUSION

- The trail drug thathuviruthikuligai on administrating to 40 patients for 48days have improved the quality of semen in count and motility.
- Expenditure of the study drug is cost effective, easily preparable and highly effective in Aanmaladu.

Sperm Count: (Ref: As per 1999 WHO criteria**)**

- Sperm count have improved to Good result by 37.5%
- Sperm count have improved to Moderate by 12.5%
- Sperm count have improved to Mild by 17.5%
- Sperm count falling with the Poor criteria by 35%

Sperm Motolity: (Ref: As per 1999 WHO criteria**)**

- Sperm motility have improved to Good result by 24%
- Sperm motility have improved to Moderate by 41%
- Sperm motility have improved to Mild by 10%
- Sperm motility falling with the Poor criteria by 25%

- Initially 50% of patients were affected from secondary sexual characters like premature ejaculation,erectile dysfunction,nocturnal emission, Painful micturition. Among them 44.4% were improved after the treatment.
- The effectiveness of the drug was assessed by the improvement of the patients from low sperm count, low motility which is measured using assessment score.
- **Inference:** The test drug is statistically significant ($p>0.0001$) and hence it is effective in the treatment of Aanmaladu.
- No adverse drug reactions were noticed during the course of treatment
- Because of the encouraging clinical and laboratory results, the study may be undertaken with the same medicines for a prolonged period in a large number of cases for the treatment of Aanmaladu.

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DEPARTMENT OF MARUTHUVAM

CLINICAL STUDY ON "AAN MALADU" (MALE INFERTILITY) AND THE DRUG OF CHOICE IS"THATHU VIRUTHI KULIGAI"

FORM I SCREENING & SELECTION PROFORMA

REG NO:

1. STUDY NO_____ 2 OP NO:_____

3.NAME :_____ 4. AGE/SEX_____5.RELIGION: H / C / M / O

6.OCCUPATION / INCOME: _____

INCLUSION CRITERIA

1. Male infertility
2. Age 21- 45 year
3. Maritial status - more than 1 year
4. Sperm count <40 Millions/Ejaculation
5. Motility less than < 50 %
6. Patient willing to sign the informed consent stating that he will conscientiously stick to the treatment during 48days but can opt out of the trial of his own conscious discretion.
7. Patients who are willing to give specimen of blood, urine and semen before and after the treatment

EXCLUSION CRITERIA

1. Azoospermia
2. Hydrocele
3. Diabetes mellitus
4. Endocrine disorders
5. Hypertension
6. Caridiac diseases
7. VDRL & STD
8. Inguinal Hernia
9. Renal diseases
10. Varicose veins
11. Systemic illness

ADMITTED TO TRAIL: YES ☐ NO ☐ If Yes Serial NO:
Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

CLINICAL STUDY ON "AAN MALADU" (MALE INFERTILITY) AND THE DRUG OF CHOICE IS

"THATHU VIRTHI KULIKAI"

FORM lI CLINICAL ASSESSMENT FORM

FORM

REG NO:

1. Study No: _____ 2. OP No: _____

3. Name: _____

4. Gender: Male

5. Age (years): _____DOB ☐☐ ☐☐ ☐☐☐☐
Date Month Year

6.Address: _____
_____
_____
_____

7.A. Occupation: ---------- B. Nature of work----------

8. Educational Status: A) Illiterate ☐ B) Literate ☐ 9. Marital status-

10. Complaints and Duration:

_____

_____

11. Habits of

A) Smoking	1. Yes; duration _____ years;	Number - 2. No
B) Alcoholism	1. Yes; duration _____ years;	Quantity- ml 2.No
C) Tobacco chewing	1. Yes; duration _____ years;	2. No
D) Betel chewing	1. Yes; duration _____ years;	2. No

E) Drugs-

12.Dietry style A. Pure vegetarian ☐ B. Non-vegetarian ☐ C. Mixed diet ☐

13.Treatment History:

Had the patient been treated before with fertility drugs? A) Yes ☐ B) No ☐

14.Previous history:

Past Medical history	(Yes/No)
Past Surgical history	(Yes/No)
Past Infertility history	(Yes/No)

If yes----------

Initial (1^{th} day) ☐ day ☐ $33^{th\ day}$ ☐ 48^{th} day

SIDDHA SYSTEM OF EXAMINATION

1. ENNVAGAI THERVU: [EIGHT-FOLD EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

NAADI	0^{TH} DAY	18^{TH} DAY	33th DAY	48^{th} DAY
VATHAM				
PITHAM				
KABAM				
VATHAPITHAM				
VATHAKABAM				
PITHAVATHAM				
PITHAKABAM				
KABAVATHAM				
KABAPITHAM				

II. NAA: [TONGUE]

	0th Day	**18th Day**	**33th Day**	**48th Day**
Colour	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal	Dark / Yellow/ Red / Pale/ Normal
Taste	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None	Sweet/ Bitter / Sour Pungent/ None
Coating	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Fissure	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Saliva	Normal/ Increased/ Decreased	Normal/ Increased Decreased	Normal/ Increased/ Decreased	Normal/ Increased/ Decreased
Dryness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Glossitis	Present/ Absent	Present /Absent	Present/ Absent	Present/ Absent
Baldness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

III.NIRAM: [COMPLEXION]

0^{th} day	18^{th} day	33th day	48^{th} day
Dark yellowtinted/wheatish brown/pale	Dark yellowtinted/wheatish brown/pale	Dark yellowtinted/wheatish brown/pale	Dark yellowtinted/wheatishbrown/pale

IV.MOZHI: [VOICE]

0^{th} Day	18th day	33th Day	48th Day
Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched	Medium/ High/ Low pitched

V.VIZHI: [EYES] (Lower palpabrel conjunctiva)

0^{th} Day	18th day	33° Day	48^{th} day
Yellow Red / Pale/Normal	Yellow Red/ Pale/Normal	Yellow Red/ Pale/Normal	

VI. MALAM; [BOWEL HABITS / STOOLS]

	0^{th} Day	18^{th} Day	33^{th} Day	48^{th} Day
Colour	Dark/ Yellow/ Pale/Others	Dark/ Yellow/ Pale/Others	Dark/ Yellow Pale/Others	Dark/ Yellow/ Pale/Others
Consistency	Solid/ Semisolid Watery	Solid/ Semisolid Watery	Solid/ Semisolid Watery	Solid/ Semisolid Watery
Stool bulk	Normal/ Reduced	Normal /Reduced	Normal/ Reduced	Normal/ Reduced
Constipation	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Diarrhoea	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent

7.URINE EXAMINATION

NEER KURI	**0^{th} Day**	**18^{th} Day**	**33 th Day**	**48^{th} Day**
Niram [Colour]	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear	White/ Yellowish/ Straw coloured/ Crystal clear
Manam [Odour]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Nurai [Froth]	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased
Edai [Sp.gra]	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced
Enjal [Deposits]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Volume	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

VIII.SPARISAM: [PALPATORY PERCEPTION]

0^{th} Day	18thDay	33thDay	48TH Day
Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat	Warmth/ Cold/ Normal/ Sweat

THEGI: [TYPE OF BODY CONSTITUTION]

Vatham predominant		Kabam predominant
Pitham predominant		Thondha udal

6.NILAM: [LAND WHERE PATIENT LIVED MOST]

1.Kurinji (Hilly terrain) ☐

2.Mullai (Plains) ☐

3.Marutham (Forestrange) ☐

4.Neithal (Coastal belt) ☐

5.Palai (Aridregions) ☐

7. KAALAM

Kaarkalam	☐	Pinpanikalam	☐
Koothirkalam	☐	Ilavenil	☐
Munpanikalam	☐	Muthuvenil	☐

8. GUNAM

Sathuvam ☐ Rasatham ☐ Thamasam ☐

IMPORIGAL (SENSORY ORGANS)

	0^{th} day	18th day	33th day	48thday
Mei (Skin)				
Vaai (Buccal Cavity)				
Kann (Eye)				
Mooku (Nose)				
Sevi(Ear)				

KANMENTHIRIYAM (MOTOR ORGANS)

Kanmenthiriyam	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Kai (upper limb)				
Kaal (lower limb)				
Vaai (buccal cavity)				
Eruvai (excretory organs)				
Karuvai (reproductive organs)				

KOSANGAL(Sheath)

Kosangal	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Annamaya Kosam				
Pranamaya kosam				
Manomaya kosam				
Vignanamaya kosam				
Ananthamaya kosam				

MUKKUTRAM: [AFFECTION OF THREE HUMORS]
A) VATHAM:

Vatham	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Praanan				
Abaanan				
Samaanan				
Udhaanan				
Viyaanan				
Naagan				
Koorman				
Kirukaran				
Devathathan				
Dhananjeyan				

B) PITHAM:

Pitham	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Analapitham				
Prasakam				
Ranjakam				
Aalosakam				
Saathakam				

C) KABAM:

Kabam	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Avalambagam				
Kilethagam				
Pothagam				
Tharpagam				
Santhigam				

13. SEVEN DHATHUS: (7 SOMATIC COMPONENTS)

Udal thathukkal	0^{th} day	18^{th} day	33^{th} day	48^{th} day
Saaram[Chyme]				
Senneer[Blood]				
Oon[Muscle]				
Kozhuppu[Fat]				
Enbu[Bones]				
Moolai [Bonemarrow]				
Sukkilam/Suronitham [Genital discharges]				

14. GENERAL EXAMINATION:

General Examination:	0^{th} day	18^{th} day	33th day	48^{th} day
Height (cms)				
Weight (kg)				
Temperature(°F)				
Pulse rate (pe rmin)				
Heart rate (per min)				
Respiratoryrate(permin)				
Blood pressure(mm/Hg)				
Pallor				

Jaundice				
Cyanosis				
Lymphadenopathy				
Pedal edema				
Clubbing				
Jugular venous pulsation				

15. SYSTEMIC EXAMINATION:

Systemic examination	0^{th} day	18^{th} day	33th day	48^{th} day
Locomotor system				
Cardio Vascular System				
Respiratory system				
Gastro Intestinal system				
Central Nervous System				
Urogenital system				
Endocrine System				

17. CLINICAL SYMPTOMS

S.no	CLINICAL SYMPTOMS	0^{th} day	18^{th} day	33th day	48^{th} day
1	Premature ejaculation				
2	Nocturnal emission				
3	Erectile dysfunction				
4	Painful coitus				
5	Painful micuturition				

Date:
Station:
Signature of the Investigator: Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDOSS PANDITHAR HOSPITAL

DEPARTMENT OF MARUTHUVAM

CLINICAL STUDY ON "AAN MALADU" (MALE INFERTILITY) AND THE DRUG OF CHOICE IS "THATHU VIRUTHI KULIGAI"

FORM III
LABORATORY INVESTIGATION ON ENROLLMENT

1. STUDY NO_____ 2 OP NO_____: REG NO:

3. NAME_____ 4. DATE OF ASSESSMENT: ----------

BLOOD INVESTIGATION		NORMAL VALUES	BEFORE TMT	AFTER TMT
HB (gms%)		M:13-18 W:11-16		
T.RBC(million cells /cu.mm)		M:4.5-6.5 W:3.5-5.5		
ESR (mm)	½ hr.	M:0-10 W:0-20		
	1 hr.			
T.WBC (cells /cu.mm)		4000-11000		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	20-35		
	Monocytes	2-10		
	Esonophils	1-6		
	Basophils	0-1		

Blood Investigation		Normal Values	Before TMT Date:	After TMT Date
Blood glucose (mg/dl)	Fasting	70-100		
	PP	80-140		
	Random	100-140		
Lipid profile (mg/dl)	Serum cholesterol	150-250		
	HDL	30-60		
	LDL	Upto 130		
	VLDL	40		
	TGL	Upto 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
LFT (mg/dl)	Total bilirubin	0.3-1		
	Direct bilirubin	0.1-0.3		
	Indirect bilirubin	0.2-0.8		
	Serum total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	Serum calcium	9-11		
	Serum phosphorous	2-5		
	SGOT (IU/L)	6-18		
	SGPT (IU/l)	3-26		
	Alkaline phosphatase mg/dl	3-12		

Special investigation:

Semen analysis:

	Before TMT (with Date)	After TMT (With Date)
Volume		
Colour		
Apperance		
Viscosity		
Liquefaction time		
Fructose		
Sperm count		
Motility		
Morphology		

Date :
Station:
Signature of the Investigator:

Signature of the HOD Signature of the Lecturer:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

AND CLINICAL STUDY ON "AAN MALADU" (MALE INFERTILITY) AND

THE DRUG OF CHOICE IS "THATHU VIRUTHI KULIGAI"

FORM - IV (DRUG COMPLIANCE FORM)

NAME:

DRUG NAME:

On 1st day-Date: Drugs issued: Drugs returned:

On 12th day-Date: Drugs issued: Drugs returned:

On 36th day-Date: Drugs issued: Drugs returned:

On 48th day-Date: Drugs issued: Drugs returned

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day25			
Day2				Day26			
Day3				Day27			
Day4				Day28			
Day5				Day29			
Day6				Day30			
Day7				Day31			
Day8				Day32			
Day9				Day33			
Day10				Day34			
Day11				Day35			
Day12				Day36			
Day13				Day37			
Day14				Day38			
Day15				Day39			
Day16				Day40			
Day17				Day41			
Day18				Day42			
Day19				Day43			

Day20				Day44			
Day21				Day45			
Day22				Day46			
Day23				Day47			
Day24				Day48			

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: ***Signature of the HOD***

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

DEPARTMENT OF MARUTHUVAM

Clinical Study on AAN MALADU (MALE INFERTILITY) and the drug of choice is"THATHU VIRUTHI KULIGAI"

FORM V – INFORMATION SHEET

Name of the Principal Investigator : Dr.P. MALAICHAMY

Name of the Institution : National Institute of Siddha, Tambaram Sanatorium, Chennai-47.

Dr.P. Malaichamy Studying M.D(S) in National Institute of Siddha, Chennai. The disease called AAN MALADU (male infertility) symptoms like premature ejaculation, erectile dysfunction, nocturnal emission, painful coitus, painful micturition This condition is being treated in NIS with many siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicines, I propose to study the thathu viruthi kuligai formulation for treating the condition. This formulation has been mentioned in siddha literature and empirical evidence with contemporary tools are required for documentation. You can receive medicines at free of cost. **"thathu viruthi kuligai"** can be taken twice daily with milk 48 days. The diagnosis tests will be carried out at free of cost. I will assess the effect of treatment after completion of 48 days of treatment using clinical and lab parameters.

- In this regard, Ineed to ask you few questions. I will maintain confidentiality of your comments and data obtained from you. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

- Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. You can choose not to answer any specific question. There is no specific benefit for you if you take part in the study, but you will be under our clinical monitoring and specific attention will be given for your health. Taking part in the study may be of benefit to the community, as it may help us to

develop medicine for aan maldu. In case of any adverse symptoms which is expected for few. patients during the treatment, shall be reported to Principle investigator and care will be taken in NIS for relief. You can withdraw from the study at the midst of treatment period, if you are not interested to continue and you will receive our regular out patient treatment without any condition.

- The information we will collect in this study, will be kept confidential remain between you and the principal investigator. We will ask you a few questions through questionnaire. I will not write your name on other investigation forms which we will sent for different investigating/analysis sections and we will use a code instead given by the principal investigator. Only the principal investigator will know the key to this code which will be kept in safe custody. If you agree to be a participant in this study, you will be screened as per the study protocol.

- If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.p. Malaichamy PG scholar (Mobile phone no 9566988615 cum principal investigator of this study, attached to the National Institute of Siddha, Chennai. You can also contact the Chairman/Member-secretary of Ethics committee, National Institute of Siddha, Chennai – 600047, Tel no: 91-44-22411611, for rights and participation in the study.

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs..... MALAICHAMY.P .....

For participating as ~~Resource Person~~ / Delegate in the Twenty First Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 25th to 29th April 2016.

Dr.N.KABILAN, MD(S),
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संस्थान
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ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 14.10.2016

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. P,Malaichamy – I year, Dept.of Maruthuvam	
Protocol Title:- An open clinical trial of a siddha herbal formulation "Thathu Virthi Kuligai" in the treatment of "Aan Maladu" (Male infertility)	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-04/ 14.10.2016**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

(Dr.V.Subramanian)
Chairman

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA CHENNAI 600 047